SEPTEMBER 4, 1985

CONSENT OF THE SENATE TO RATIFICATION
VIENNA CONVENTION FOR THE PROTECTION OF THE OZONE LAYER

TO THE SENATE OF THE UNITED STATES:

I transmit herewith, for the advice and consent of the Senate to ratification, the Vienna Convention for the Protection of the Ozone Layer. The report of the Department of State, the final act of the conference that adopted the Convention, and an environmental assessment and finding of no significant impact are enclosed for the information of the Senate.

The convention provides a foundation for global multilateral undertakings to protect the environment and public health from the potential adverse effects of depletion of stratospheric ozone. The Convention addresses this important environment issue primarily by providing for international cooperation in research and exchange of information. It could also serve as a framework for the negotiation of possible protocols containing harmonized regulatory measures that might in the future be considered necessary to protect this critical global resource.

The Convention, which was negotiated and adopted under the auspices of the United Nations Environment Program (UNEP), will be an important step toward protecting and enhancing public health and the quality of the global environment. The United States played a leading role in the negotiation of the Convention. Expeditious ratification by the United States will demonstrate our continued commitment to progress on this significant environmental issue.

I recommened that the Senate give early and favorable consideration to the Convention and give its advice and consent to ratification.

RONALD REAGAN

THE WHITE HOUSE
September 4, 1985

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 76N-0460]

CERTAIN FLUOROCARBONS (CHLOROFLUOROCARBONS) IN FOOD, FOOD ADDITIVE, DRUG, ANIMAL FOOD, ANIMAL DRUG, COSMETIC, AND MEDICAL DEVICE PRODUCTS AS PROPELLANTS IN SELF-PRESSURIZED CONTAINERS

Prohibition on Use

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This final rule prohibits the use of certain fluorocarbons, the fully halogenated chlorofluoroalkanes (chlorofluorocarbons), as propellants in self-pressurized containers in products subject to the Federal Food, Drug, and Cosmetic Act (hereafter, "the act"). This action is being taken because chlorofluorocarbons may deplete stratospheric ozone, leading to an increase in skin cancer, climatic changes, and other adverse effects. Essential uses of chlorofluorocarbons, specified in the regulation, will not be subject to the regulation.

EFFECTIVE DATES: Food, drug, device, or cosmetic products manufactured or packaged on or after December 15, 1978, and finished products initially introduced into interstate commerce on or after April 15, 1979, must comply with the regulation.

FOR FURTHER INFORMATION CONTACT:

1. Science: David S. Klauder, Environmental Impact Staff (HFS-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4500.

2. Legal: Margaret Gilhooley, Office of General Counsel (GCF-1), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-1345.

3. Economic: Gail Updegraff, Office for Planning and Evaluation (HFP-14), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-6250.

4. Regulatory: (a) Food and Cosmetics: Richard Aker, Bureau of Foods (HFF-302), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1254. (b) Human Drugs: Paul Fehnel, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-6490. (c) Animal Drugs: Robert Brigham, Bureau of Veterinary Medicine (HFV-238), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-6243. (d) Devices: Harry Butts, Bureau of Medical Devices (HFK-110), Food and Drug Administration, Department of Health, Education, and Welfare, Silver Spring Plaza, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7218.

SUPPLEMENTARY INFORMATION:

Related Actions

1. A final rule published in the Federal Register of April 29, 1977 (42 FR 22017) that requires warning statements on foods, over-the-counter (OTC) drugs, animal food, animal drugs, cosmetics, and medical devices in self-pressurized containers that contain chlorofluorocarbon propellants has been in effect since October 31, 1977.

2. The Environmental Protection Agency (EPA) plans to promulgate a final rule to prohibit, under the Toxic Substances Control Act, the manufacture, processing, and initial distribution in commerce of chlorofluorocarbons for aerosol propellant uses except for specified essential uses.

3. The Consumer Product Safety Commission (CPSC) published in the Federal Register of August 24, 1977 (42 FR 42780) a final rule to require that aerosol products subject to the Consumer Product Safety Act that contain chlorofluorocarbon propellants carry a warning label statement. The effective date of this regulation is February 20, 1978.

4. The Food and Drug Administration (FDA), along with EPA and CPSC held a public meeting on October 25-27, 1977, to collect information on nonpropellant uses of chlorofluorocarbons, e.g., in refrigeration, air conditioning, plastic foam blowing, or as solvents, anesthetics. An additional public meeting on nonpropellant uses of chlorofluorocarbons is scheduled for February 21-24, 1978. Notices of this joint public meeting were published in the Federal Register of January 13, 1978 (43 FR 1986, 1997). The information obtained at these meetings will be used in the consideration of regulatory decisions relating to nonpropellant uses of chlorofluorocarbons.

Background

The prohibition on the use of chlorofluorocarbons established by this rule was proposed in the Federal Register of May 13, 1977 (42 FR 24535). The products to which the regulation applies are human foods, human drugs (including biological products), animal foods, animal drugs, cosmetics, and medical devices. The prohibition does not apply to uses, specified in the rule, that the Commissioner has concluded are essential.

The Food and Drug Administration is issuing this regulation to reduce the risk of injury resulting from stratospheric ozone depletion posed by the release of chlorofluorocarbons. A reduction of stratospheric ozone would increase the amount of biologically damaging ultraviolet radiation reaching the Earth, and as a result might increase the incidence of skin cancer, change the climate, and produce other adverse effects. Chlorofluorocarbon release might also affect the climate by increasing infrared absorption in the atmosphere.

The Commissioner of Food and Drugs took the initial steps toward phasing out the use of chlorofluorocarbons in products subject to the act in a proposal to require warning statements (Docket No. 76N-0459), and in a notice of intent to propose rules and request for information (Docket No. 76N-0460), which were published in the Federal Register of November 26, 1976 (41 FR 52071 and 52070, respectively). The preamble to the proposal to require a warning set forth the Commissioner's reasons for believing that regulatory action is necessary to phase out nonessential uses of chlorofluorocarbons. The final rule requiring a warning statement on products containing nonessential chlorofluorocarbon propellants subject to the act, except for prescription drugs for use in humans, was published in the Federal Register of April 29, 1977 (42 FR 22017). In the preamble to the final rule, the Commissioner discussed the comments received on the proposed warning statement.

In the Federal Register of May 13, 1977 (42 FR 24535), the Commissioner published the proposal to phase out nonessential uses of chlorofluorocarbon propellants. The Commissioner relies on the administrative record relating to the regulation to require a warning statement and this regulation, Docket Nos. 76N-0459 and 76N-0460, to support and demonstrate the need for this final regulation to prohibit the nonessential uses of chlorofluorocarbons as propellants in self-pressurized containers in products subject to the act.

Applicability of Regulation

The final regulation contains a provision limiting the applicability of the regulation to the use of chlorofluorocarbons in whole or in part as a propellant to expel from the same con-

tainer or from a different container other liquid or solid contents under pressure.

The effective dates of this regulation are the same as those set forth in the proposal. The scope of this FDA regulation is not significantly different from that set forth in the May 13, 1977, proposal. The following items are included in this final regulation that were not part of the proposal: (1) An additional use of chlorofluorocarbon propellants determined to be essential, i.e., use in metered-dose ergotamine tartarate drug products for oral inhalation, (2) a use previously determined to be essential, i.e., in sytological fixative sprays, now classified as nonessential and therefore subject to this regulation, (3) a provision to allow studies to continue after December 15, 1978, on the use of chlorofluorocarbon propellants in investigational new drug products likely to be considered essential, and (4) additional discussion in the preamble to the regulation (comment 37) and a slight modification in § 2.125(a)(2) of the regulation to indicate more clearly that all nonessential uses of chlorofluorocarbon propellants are subject to this regulation, including those cases in which chlorofluorocarbons in one container are used to propel the active ingredients in a separate container.

Response to Comments on Proposal

Seventy submissions were received on the May 13, 1977, proposal to phase out nonessential uses of chlorofluorocarbon propellants. These comments came from other Federal agencies, State agencies, legislators, industries, professional societies (e.g., American Medical Association, American Chemical Society), churches, scientists, physicians, veterinarians, students, and concerned citizens. For convenience, the responses to these comments have been divided into seven major groupings: I. General Issues; II. Scientific Overview; III. Specific Scientific Issues; IV. Legal Issues; V. Economic Issues; VI. Essentiality Issues; and VII. Alternatives.

I. General Issues

Thirty-four general submissions were received. Of these, 27 supported the proposed action; 7 opposed; and 1 expressed general views without taking a position. The American Medical Association adopted a resolution commending the Federal Government for its efforts to prohibit the sale of chlorofluorocarbons in aerosol cans.

1. Among those supporting the regulation, many expressed a general concern for the lack of knowledge about the full extent of the damage to the public health and the environment that might result from chlorofluorocarbon emissions. Until the consequences are better understood, the comments urged that the production and use of these compounds be reduced as much as possible. The major reason given by those opposing the proposed regulation, however, was also that there are too many unknowns and uncertainties in the current predictions of potential effects resulting from chlorofluorocarbon emissions. One comment characterized the evidence against chlorofluorocarbons as pure conjecture, and held that the threat posed is mild as compared to those from alcohol and tobacco.

The Commissioner believes that the available information indicates that chlorofluorocarbon release poses a risk of significant harm, notwithstanding the existence of some uncertainties which may make the consequences greater or less than currently estimated. The Commissioner has dealt with this issue in greater detail in response to those making specific comments on scientific uncertainties (see section IIIA).

2. Another frequently expressed comment among those supporting the proposed regulation was that the agency was allowing too much time before the effective date of the phaseout. It should be noted that the agency also received comments requesting extension of the effective date and has addressed these in sections III-V.

Based upon the information presented in the National Academy of Sciences' (NAS) reports (refs. 1, 2), the National Aeronautics and Space Administration Worksnop and assessment reports (refs. 3, 4), the FDA environmental impact statement (ref. 5), and the FDA inflation impact statement (ref. 6), the Commissioner has attempted to set an effective date for the regulation that would reduce the risks associated with chlorofluorocarbon emissions from nonessential aerosol propellant uses to the greatest extent possible and as soon as possible, and to allow time for an orderly phaseout. In addition, this phaseout regulation has been coordinated with the actions of other Federal agencies in order to establish a unified Federal program and uniform effective dates.

3. Several comments cited the availability of suitable alternatives to aerosol propellants containing chlorofluorocarbons, though some noted an inconvenince in using alternatives.

The Commissioner believes that alternatives to nonessential chlorofluorocarbon sprays do exist, and that any convenience is small when compared to the risks of continued chlorofluorocarbon emissions (section VII).

4. Some people revealed concern and anger that their children might suffer health and environmental consequences because "someone proposed an easier way for people to get through a day." The comments criticized the failure to correct the problem much earlier.

It is true that most chlorofluorocarbon-induced health and environmental effects, should they occur, would largely be borne by children and future generations. However, these environmental and indirect health risks were only recently established. At any point in time the agency can only make decisions based on the best available science and technology. Now that risks have been documented, the Commissioner is acting to prevent the possibility of further adverse impacts resulting from the nonessential uses of chlorofluorocarbon propellants.

5. Two comments expressed support for the proposal because it would solve the aerosol "sniffing" problem that has resulted in injury and death to many who have attempted to get a "high" by intentionally inhaling products containing chlorofluorocarbons.

Although this action is not being taken to protect against direct health effects, the Commissioner notes that this issue has been of concern to the agency. A final regulation requiring a label warning against misuse was promulgated in 1975, e.g., 21 CFR 740.11.

6. One individual noted that the problem is global in nature and asked what efforts are being made at the international level to reduce chlorofluorocarbon emissions. The international scope of the problem was the subject of two additional comments. They pointed to the fact that most nations have not yet initiated regulatory procedures to reduce emissions of chlorofluorocarbons and stated that this fact supported the position to delay U.S. regulations.

The Commissioner notes that recognition of the possibility of damage to the oxzone layer from human activities has been widespread in the international community for some time. In relation to the specific threat posed by chlorofluorocarbons, the publication and wide distribution of the National Academy of Sciences' reports (refs. 1, 2) stimulated considerable international interest. As in the United States, there are differences of opinion within and among countries concerning the urgency of the threat and the need to take early remedial action. However, it was explicitly recognized in the final report of the March 1977 international scientific meeting on the ozone layer, sponsored by the United Nations environment program (ref. 7), that "CFM[1] emissions are a matter of concern." The consensus of the April 1977 meeting of policy level officials on the reg-

[1]CFM: chlorofluoromethane, a class of chlorofluorocarbons containing one carbon atom, e.g., F-11 (CCl_3F) and F-12 (CCl_2F_2).

ulation of chlorofluorocarbons (ref. 8), attended by 13 of the world's leading producers and users of chlorofluorocarbons, was also that the issue of ozone depletion is a serious one that requires close attention.

7. The American Chemical Society, a professional organization, commented that the proposed regulation failed to provide a timely review mechanism and a "time base that allows the community effort to assess and alleviate the problem." The comment described the proposal as the first instance in which a regulation had been based on "unverified scientific projection," a basis described as "a very dangerous precedent." The comment noted that individual chemists found the effects of chlorofluorocarbon release to be "a cause for concern," apparently more with respect to climatic, agricultural, and ecosystem consequences than with respect to the risks of skin cancer. This concern was thought to warrant further research and continual monitoring. The comment expressed the opinion that, during the upcoming period of making measurements to test the validity of model predictions, the agency "should not respond to every prediction," and noted the "very limited" impact on the stratospheric ozone concentrations from 1 year or 2 delay. The comment expressed agreement with the general goal of protecting the public from unreasonable risks, and noted that the regulation of chlorofluorocarbons poses "a very difficult problem."

The Commissioner agrees with many of the principles cited in the submission. He recognizes that it is important to have experimental testing of scientific models and that it would be inappropriate to respond to every prediction of ozone depletion. In the case of chlorofluorocarbons, the scientific models underlying the regulatory action have undergone careful and intensive scientific scrutiny by government, academic, and industry scientists. Several components of these models have been tested and validated. The complexities of the subject make full verification difficult and timing of full verification uncertain. The Commissioner notes in particular that he finds the increased risk of nonmelanoma skin cancer as a consequence of depletion to be of serious concern; this view may account for the differences between his assessment and the individual views reflected in this comment. Under the law, the agency need not wait for actual injury to occur before acting to protect the public. The Commissioner believes that, notwithstanding some uncertainties and the absence of complete experimental testing, the available information establishes an unreasonable risk of injury that warrants regulatory action at this time.

The Commissioner believes that the regulation provides an adequate time basis and framework for taking account of new developments. The Commissioner will promptly take action to stay the regulation or withdraw it if further research shows that such action is warranted. Under the agency's procedural regulation, 21 CFR 10.30, any person can file a petition to request revocation of a regulation. Furthermore, periodic reports will be made by EPA and other agencies, pursuant to the Clean Air Act Amendments, of research developments and Federal regulatory actions. EPA and FDA will also be undertaking a consideration of a control of chlorofluorocarbon emissions from nonpropellant uses. That effort will necessitate a continued monitoring and reassessment of any developments relating to ozone depletion. Consequently, a specific review mechanism in the regulation is not needed.

II. Scientific Overview

Many comments requested the agency to delay the issuance of the final regulation to await further research and evaluations that would explore the scientific uncertainties about the effects of chlorofluorocarbon release on ozone depletion. A major manufacturer of fluorocarbons requested a delay for further research for the 1- or 2-year period recommended in the NAS Committee report (ref. 1). The comment also stated that "substantial new findings" could result from ongoing research, and requested a delay in promulgation of the regulation until June 1978, without extending the effective dates, to permit a reassessment of the data by the NAS Committee. Other comments suggested that a 2- or 3-year delay would be reasonable.

These comments based their recommendation for a delay on some or all of the following points: (1) Uncertainty in the estimates of ozone depletion and its effects, including some uncertainties brought out by recent research, (2) the absence of empirical evidence validating the scientific models and establishing that stratospheric ozone is in fact being depleted, (3) the NAS Committee's original recommendation that there could be up to a 2-year delay to permit further research, (4) the small amount of ozone depletion and consequent injury that would occur from delay for a short period, (5) the reduction in the amounts of chlorofluorocarbons used as propellants over the past 3 years, and (6) the possibility that the monitoring of ozone depletion through trend analysis would detect depletions of ozone levels in time to limit the amount of ultimate ozone depletion to a certain "acceptable" amount.

The Commissioner has discussed below in more detail (section III.A) the specific scientific uncertainties and research needs raised in the comments and the available information about these developments. In addition, the Commissioner continues to rely on the supporting material and responses already in the record relating both to this action and to the regulation to require a warning statement. Discussed in this section is the general response to the underlying argument made by those comments opposing the regulation, that the risk of ozone depletion and harm from chlorofluorocarbon release is so uncertain that regulatory action to prohibit the nonessential uses of chlorofluorocarbon propellants is unwarranted at the present time and should be delayed for various suggested periods, ranging from 6 months to 3 years, in order to permit further research and evaluation.

The agency is aware that there are uncertainties about the extent of ozone depletion from chlorofluorocarbon emissions, and the consequences of depletion, and that there may be unknown processes that could reduce depletion estimates below the lowest current estimates or conceivably establish that no depletion occurs. The NAS Panel and Committee pointed out the existence of uncertainties in the reports upon which the agency has relied (Refs. 1, 2). Virtually all of the areas of uncertainty and research needs raised in these comments were discussed in the NAS (Refs. 1, 2) and recent National Aeronautics and Space Administration (Refs. 3, 4) reports, as is indicated in the detailed responses to follow.

The agency has also recognized that the NAS Committee report recommended a "strictly limited delay" of up to 1 or 2 years from September 1976 to conduct the research that would reduce the "undeterminable uncertainties." In the preamble to each of the earlier documents published in the Federal Register of November 26, 1976, April 29, 1977, and May 13, 1977 (41 FR 52071, 42 FR 22017, and 42 FR 24537, respectively) requiring a warning and proposing a phaseout of nonessential chlorofluorocarbon propellant uses, the agency has extensively discussed the reasons for initiating regulatory action notwithstanding the existence of scientific uncertainties and the recommendations for more research. In brief, the agency has acted because the best estimates of the scientific community after careful examination are that chlorofluorocarbon release leads to a reduction of stratospheric ozone, that the ultimate consequences of ozone depletion at the estimated levels are unacceptable in the agency's judgment, and that it is indefinite when the remaining scientific questions will be conclusively resolved. As previously indicated in these preambles and in FDA's environmental

impact statement, a delay in regulatory action poses a risk of additional nonmelanoma skin cancer and other adverse effects. The subsequent scientific developments have not materially altered the agency's overall assessment of the need for action.

Since the issuance of the proposed prohibition, the National Aeronautics and Space Administration issued in September 1977 final workshop and assessment reports (Refs. 3, 4) evaluating the stratospheric effects of chlorofluorocarbon releases. These reports represent the current knowledge as of June 1977 relating to the effects of chlorofluoromethanes on stratospheric ozone. The final National Aeronautics and Space Administration assessment report states that the predictions of the modeling groups active in the field "cover a range of ozone depletions from 10.8 percent to 16.5 percent. This range is the current best estimate for ozone depletion from continued (chlorofluorocarbon 11 and 12) releases at the 1975 release rate." The National Aeronautics and Space Administration assessment also noted the uncertainties of the assessment. Using the NAS procedure for estimating uncertainties, "the overall uncertainty range is 4 percent to 30 percent."

Therefore, the best estimates, based on currently known information, of the amount of ultimate ozone depletion from release of chlorofluorocarbons at 1973-1975 rates are even higher than those made in the NAS report. The risks of nonmelanoma skin cancer and other adverse effects are now greater than those estimated in FDA's environmental impact statement (Ref. 5), even in light of reported decreases in propellant uses of chlorofluorocarbons. Thus, the current estimates of ultimate ozone depletion provide additional reason to phase out the nonessential uses of chlorofluorocarbon propellants in an orderly fashion without delay.

The Federal government, as well as industry, has been sponsoring a considerable amount of research to improve the understanding of man-induced modifications of the stratosphere and their effects on biological systems and the climate. The statutory provisions in the Clean Air Act Amendments of 1977 (42 U.S.C. 7450 et seq.) require the NAS and Federal agencies to provide continuing updates of scientific developments.

In response to this statutory provision, the NAS issued a report (Ref. 9) on December 19, 1977, updating the scientific knowledge about the effects of substances and activities which may affect the stratosphere, especially ozone in the stratosphere. The report contains the following summary of the scientific developments and some of the remaining uncertainties:

At present, the major threat to the ozone layer is from the releases of F-11 and F-12. There are no new developments that suggest that the effects will be smaller than the ones outlined in our previous report; in fact, as noted above, the best available figure is about twice what the best figure was in 1976.

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The new values of the rate constants have produced some inconsistencies between the model calculations and a number of the stratospheric measurements. There are also some serious problems in explaining some of the recent ClO measurements and the latitudinal and temporal dependencies of NO_x. Until these problems are resolved, the quantitative predictions of the models including the allowances for recognized uncertainties (e.g., those in the NASA report) must still be viewed with reasonable caution.

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It is unfortunately true, however, that, accompanying very substantial overall progress, the recent development of our understanding of stratospheric chemistry has been dominated by major upheavals caused by the recognition of the importance of processes whose role either had not been properly appreciated (such as the addition of chlorine nitrate chemistry, which delayed the publication of the previous panel report) or whose rate coefficient had been grossly misjudged (such as the rate constant for the important reaction $HO_2+NO \rightarrow HO+NO_2$, whose recently established larger value has made chlorine catalysis of ozone much more effective than previously thought and NO_x catalysis less so). To say how many more major upheavals we should expect in the future is rather like trying to foresee the unforeseeable. Yet it is certainly true that there is less and less likelihood of future such major upheavals. (Footnote omitted.)

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The recommendation made in the NAS report that action to limit releases of CFM's should be delayed for a period up to 2 years was made, in part, because a number of atmospheric measurements were expected to be made during that period, which, it was believed, would decrease the uncertainties in the predictions of the effects of CFM's on stratospheric ozone. A number of these measurements have indeed been made. While the results of these measurements do confirm many aspects of the model, they have also raised some new, unanswered questions. Some ambivalence in interpretation of isolated measurements is not too surprising in a system as complex as the earth's atmosphere.

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The most serious health consequence of possible stratospheric change still seems to be possible or probable increases in death from malignant melanoma (a type of skin cancer).

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Increased DUV would increase the incidence of basal- and squamous-cell carcinomas, a less serious, rarely fatal, but much more prevalent form of DUV-induced skin cancer. This increased incidence would result in serious disfigurement and an increased economic burden.

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Thus, the NAS update confirms that the best current estimates indicate that continued release of chlorofluorocarbons at 1973 rates would lead to a significant decrease in stratospheric ozone. The availability of this NAS update would seem to meet the comments that urged the agency to delay issuing a final regulation to permit a reassessment by the NAS committee. The Commissioner agrees with the NAS update report (Ref. 9) that there are remaining scientific uncertainties, and that the estimates of depletion have to be viewed with "reasonable caution." The regulatory course adopted by the agency is an appropriate one in this situation. The agency has undertaken a gradual phaseout. Only nonessential propellant uses are affected by the current action. The agency remains committed to monitoring scientific developments and taking prompt action if further research indicates that chlorofluorocarbon release does not significantly affect the stratosphere, human health, and the environment.

The Commissioner recognizes that this scientific field is unusually complicated and that there are and may continue to be uncertainties about the estimates and the models. There are natural fluctuations in stratospheric ozone levels which complicate efforts to determine the trend and validate model predictions. There are difficulties in standardizing measurements. Much work has been done in recent years to reduce the uncertainties. As happens in science, further research may open up new questions that have to be explored before a definitive answer emerges.

The principal area of uncertainty that could significantly affect whether regulatory action is needed lies in the possibility that there are chemical processes or reaction rates not now known that would reduce the current estimates of the effects of chlorofluorocarbons on stratospheric ozone to some insignificant level. It is not now possible to estimate how significant these matters are or how long it would take to evaluate their significance. During any delay to await answers, the public would continue to be exposed to a greater risk of nonmelanoma skin cancer and other effects resulting from a depletion and/or redistribution of stratospheric ozone.

Because the best available information indicates that the nonessential propellent uses of chlorofluorocarbons pose a risk of injury that the Commissioner regards as unacceptable, the Commissioner is proceeding to issue the final regulation. The prohibitions on the use of chlorofluorocarbons in

aerosol products begin in late 1978. The effective date falls after the expiration of the maximum 2-year time period originally recommended by the NAS Committee for further research. The Commissioner will give prompt attention at any time to any new developments that warrant delaying the effective dates or withdrawing the final regulation. He believes this is a reasonable way to take into account both the continuing uncertainties, the ongoing research and the need to protect the public from an unreasonable risk of injury.

III. Specific Scientific Issues

A. *Uncertainties of Stratospheric, Biological, and Climatic Effects: Requests for Delay to Await Further Research.* 8. One comment concluded that there would be no depletion of stratospheric ozone secondary to chlorofluorocarbon releases because any ozone destroyed would increase the amount of the sun's radiation passing through the stratosphere, which would in turn increase the generation of new ozone from oxygen.

Indeed, ozone regeneration as described in the comment does occur and is taken into account in present one-dimensional models (Refs. 2 and 3). This negative feedback mechanism, referred to as the "self-healing" effect, is expected to result in an increased rate of production of ozone in the lower stratosphere (around 20 kilometers (km)) secondary to a large chlorofluorocarbon-induced decrease in the percent of ozone at about 30 to 40 km. Even so, current models predict that the ozone levels in the lower stratosphere will be slightly decreased with respect to natural levels. Therefore, the so-called "self-healing" effect is not complete and an overall net decrease in column ozone would remain. Current predictions are that this ultimate net reduction of stratospheric ozone resulting from continuous chlorofluoromethane emissions at 1975 release rates would be in the order of 10.3 to 16.5 percent (Ref. 3, pp. 189-195). Even if all the ozone destroyed by chlorofluorocarbons were completely regenerated, the redistribution of stratospheric ozone itself could produce changes in global climatic patterns of unknown nature and magnitude.

9. Eleven submissions raised the issue of existing uncertainties in the theory that chlorofluorocarbons released into the atmosphere will deplete stratospheric ozone. The comments viewed these uncertainties as reason to defer the regulation or to delay its effective dates. Specific areas of uncertainty mentioned were the following:

(a) *Effects on Stratospheric Ozone.*

(1) *Uncertainties in reaction rate data.*—Several comments stated that uncertainties exist in the rates of many key reactions, particularly for $NO+HO_2$ and for the photochemistry of NO and O_2 and that inaccurate reaction rates could lead to errors in calculating the effects of chlorofluorocarbons on stratospheric ozone. One comment stated that "the reactions of HO_x account for the largest uncertainty in current model chemistry."

The Commissioner is aware that uncertainties exist in current reaction rate data which are used in models predicting the stratospheric effects of chlorofluorocarbon release. The National Aeronautics and Space Administration (NASA) discussed the data base for each of its recommended reaction rates (Ref. 3, pp. 1-25) and concluded that uncertainties remain. An important point, though, is that the uncertainties relate to the extent of ozone depletion and not to the fact that ozone is being destroyed by chlorinated compounds which enter the stratosphere. Revised reaction rates since the September 1976 NAS reports (Refs. 1, 2) point to greater ozone depletion. The recent direct measurement of the $NO+HO_2$ reaction rate raised by a factor of 30 the previously recommended rate based on laboratory measurements (Ref. 3, pp. 17-18). The significance of this finding is reflected in the NASA statement, "When the new $NO+HO_2$ rate is used, all of the models (1-D temperature coupled) showed an increase in the calculated column-ozone depletion due to continued CFM release at 1975 rates of about a factor of 2 so that the range is from 10.3 to 16.5 percent." (Ref. 3, p. 192.) It would not be unexpected if further research resulted in the need to revise other recommended reaction rates. The NASA assessment found that "the reaction rates given in the workshop report are close to those recommended in the NAS report and reflect the best information available to date." (Ref. 4, p. 9.) The NASA workshop also assessed the uncertainty associated with reaction rate measurements and estimated it to be "a factor of 2.8 on the low side and a factor of 1.8 on the high side." (Ref. 4, pp. 9-10.)

(2) Tropospheric and stratospheric "sinks" not yet adequately quantified.—As noted in a few comments, the formation of chemical species leading to the temporary or permanent removal from the atmosphere of active or potentially active forms of chlorine would reduce the magnitude of predicted ozone destruction from chlorofluorocarbons. Additionally, secondary reactions which affect the rate of the above reactions may also act indirectly as "sinks" reducing the effects of chlorofluorocarbons on stratospheric ozone. The comments suggested that current models may not include or adequately account for all "sinks," such as the degradation of chlorofluorocarbon 11 to hydrochlorofluorocarbon 21, the degradation of chlorofluorocarbons absorbed to silica particles, and the formations of chlorine nitrate ($ClONO_2$) and peroxynitric acid (HO_2NO_2).

The Commissioner agrees that the possibility exists that the conversion of chlorofluorocarbon 11 to hydrochlorofluorocarbon 21 is a tropospheric sink. Laboratory measurement instruments indicate the presence of hydrochlorofluorocarbon 21 in tropospheric air samples at part-per-trillion levels. These levels cannot be accounted for on the basis of hydrochlorofluorocarbon 21 emissions data. In the response to a similar comment in the final warning statement regulation (see the Federal Register of April 29, 1977 (42 FR 22022)), it was suggested that the presence of hydrochlorofluorocarbon 21 in tropospheric air samples is probably the result of instrumental contamination. Dr. H. B. Singh, one of those who made the above measurements, states that the most likely explanation is that minute amounts of chlorofluorocarbon 11 are being degrated to hydrochlorofluorocarbon 21 within the measuring equipment (Ref. 10). If this is the case, actual chlorofluorocarbon 11 concentrations in the troposphere would be higher than measured levels, a factor which would increase the tropospheric lifetime of this compound and also the present estimates of ultimate ozone reduction.

Regarding the possibility of tropospheric removal of chlorofluorocarbon 11 by photolysis when contact is made with sand, NASA states, "Quantitative evaluation is not yet possible." (Ref. 3, p. 179).

Current one-dimensional models used to describe the effects of chlorofluorocarbons on stratospheric ozone have taken into account effects due to the formation of chlorine nitrate as they are now understood. Upper limits to the abundance of chlorine nitrate ($ClONO_2$) in the stratosphere have been established (Ref. 3, p. 176), but its mixing ratio[1] is not well understood (Ref. 3, p. 100).

NASA acknowledges that peroxynitric acid (HO_2NO_2) is a potential sink for NO_x (and HO_x) in the atmosphere which would reduce current estimates of ultimate ozone depletion, but then states that "* * * peroxynitric acid should not be introduced into atmospheric models until there is also kinetic information on its photolysis and reactions with atoms and free radicals; it may be an ineffective sink." (Ref. 3, p. 16.)

NASA concludes its discussion of possible tropospheric sinks as follows:

[1] Mixing ratio: Density of a chemical species divided by the density of the total atmosphere at a given altitude.

In summary, no significant inactive removal processes have been suggested for F-12. For F-11, the combined effects of two possible 70-year sinks—solution in the oceans and ion-molecular reactions—could reduce the steady-state concentration of F-11 by 60 percent. However, because F-11 contributes only approximately one-third of total ozone depletion of CFM's, a 60 percent decrease in its steady-state concentration will result in only approximately 20 percent reduction in predicted ozone depletion." (Ref. 3, pp. 184–185.)

The NASA workshop report also indicates "that more studies and measurements are needed to obtain better estimates of the oceanic removal times for F-11 and F-12." (Ref. 3, p. 181.)

The Commissioner reemphasizes his intent to monitor closely the scientific developments relating to significant tropospheric and stratospheric sinks for chlorofluorocarbons.

(3) Uncertainties due to approximations of transport parameters—Two comments stated that the treatment of atmospheric motion and the transfer of chemical species is over-simplified in one-dimensional (1-D) models and subject to large errors. It was also noted that various models use different parameters to approximate the transport of chemical species.

The Commissioner understands that 1-D models do not fully account for the transport of substances to and from the stratosphere. However, regarding the vertical transport of chlorofluorocarbons, NASA states "Because of the expected uniform mixing of CFM's in the troposphere, the uncertainties in vertical transport resulting from the use of a 1-D model are relatively small." (Ref. 3, p. 226.) As recognized by NASA, the so-called eddy diffusion parameter is the best available estimate of transport processes until multi-dimensional analyses are perfected (Ref. 3, pp. 134–138, 208–229, and Ref. 4, p. 10). The NASA assessment report makes the statement that "This approximation, while probably not leading to great errors, should increase the uncertainties from that quoted in the NAS report * * *. The overall conclusion then is that the uncertainty in the assessment due to the approximation in dynamics implied by the use of a 1-D model is at least the factor of 1.7 quoted in the NAS report. A more detailed estimate must await further studies using multi-dimensional models." (Ref. 4, p. 10.)

(4) Uncertainties due to model chemistry—Inadequacies in the chemistry introduced into 1-D models were the subject of several comments. Specifically mentioned was that (a) several field measurements differ from model predictions, i.e., those for O_x, OH, HCl, and ClO at specific altitudes, (b) certain atmospheric species, i.e., ClONO, and HO_xNO_x, have not been adequately quantified, (c) simultaneous measurements of various chemical species in the atmosphere are needed to validate model chemistry, and (d) there may be additional missing chemistry.

Regarding expected and observed ozone levels (item 4(a) above), several manufacturers cited a four-fold discrepancy between the mid-latitude ozone profile projected by the models and measured ozone concentrations based on satellite data. Specifically, one satellite has recorded levels of ozone at 50 km which are four times the value calculated in current models. Some rocket measurements are also twice as high as model calculations at this altitude. Additionally, differences exist between calculated and observed ozone levels at altitudes above 35 km using the Umkehr method.*

The comments stated that one-dimensional models should be more reliable at this upper region of the stratosphere so that these discrepancies "give greater weight to the possibility of serious inadequacies" in the models that perdict ozone depletion. It was pointed out that the NAS Panel considered the one-dimensional models reliable on the basis of their ability to predict mid-latitude ozone profiles.

Regarding differences between field measurements and model predictions in general, it should first be noted "* * * that comparison of the 1-D model results with specific species measurements should not be expected to be better than a factor of 2 or 3 because of the assumptions inherent in time and spatial averaging and in representing transport—in the diffusion approximation." (Ref. 3, p. 193.)

The measurements cited in the comments were known at the time of the NASA assessment. Other satellite and rocket measurements are in general agreement with model predictions at other altitudes. Regarding estimates of ozone depletion above 35 km using the Umkehr method, NASA notes that this method is "less precise" than satellite measurements (Ref. 3, p. 76).

The NASA report states (Ref. 3, p. 194):

> A further difficulty encountered in comparing 1-D model results to measurements is the upper stratospheric-ozone profile. Above about 30 kilometers, time constants for odd-oxygen destruction become sufficiently short for one to expect a near chemical equilibrium situation, and the model results should be a reasonably accurate representation of the atmosphere in this region. In the 30- to 40-kilometer region, this appears to be so when measurements at mid-latitudes are compared to model results. However, near 50 kilometers altitude, the models appear to give consistently lower values than are measured. A further uncertainty is the apparent disagreement between different measurement techniques at this altitude. Until this is resolved, it is not clear exactly how large the actual ozone concentration is at 50 kilometers and above. It is clear that the model results with the current evaluation of rate constants are less than all of the measurements. Some attempts have been made to adjust model inputs in order to lessen this discrepancy. These yield results for ozone depletion generally within the ranges already quoted. The adjustments made are arbitrary, and it is not clear at this time which, if any, are correct.

Above 50 km the contribution to total ozone is small. Therefore, as noted above, a wide range of ozone values at 50 km can be introduced into current models without significantly affecting ozone depletion estimates. Additional ozone measurements will undoubtedly resolve this apparent conflict.

The Commissioner recognizes the variability between field measurements and model predictions for other chemical species, i.e., for OH, HCl, and ClO, but notes that much of this may be due to natural fluctuations. Hydrogen atom species (HO_x) in the lower stratosphere "are strongly affected by the distribution and variability of the hydrogen atom source compounds—water vapor, molecular hydrogen, and methane. For example, enough water-vapor measurements have been made to verify its extreme variability in the lower stratosphere, and HO_x concentrations will reflect this variability to a large extent." (Ref. 3, p. 153.)

Measurements of hydrogen chloride (HCl) and chlorine oxide (ClO) have also shown these species to be variable. By appropriately varying the concentrations of other species that influence HCl and ClO, current models can predict the observed concentrations of both species. However, the observed variations in HCl and ClO are not well understood. The NAS update report emphasizes the significance of the currently available Cl and ClO measurements (Ref. 9, p. 23) and the need for additional such measurements, particularly those made simultaneously with other photochemically related species, in order to determine the nature of the apparent conflict between measured and expected ClO concentrations (Ref. 9, p. 24).

NASA's treatment of ClONO, and HO_xNO_x (item 4(b) above), has been discussed under item 9(a)(2) tropospheric sinks. Research is ongoing to better quantify these atmospheric species.

The Commissioner understands the emphasis now being placed on the need for simultaneous measurements of temperature, O_x, and the photochemically related ClO_x, HO_x, and NO_x species (item 4(c) above). All of these stratospheric species and temperature exist in a dynamic state such that an accurate representation of the interaction among them can only be deter-

*Umkehr method: An old method for measuring the vertical distribution of ozone based upon the variation in the absorption by ozone of two wavelengths as a function of the position of the sun.

mined by making simultaneous measurements. A few simultaneous measurements have been made (Ref. 3, pp. 109–119) and most compare reasonably well with model predictions. Additional such measurements are planned, and the Commissioner will monitor the results obtained.

Though the possibility cannot yet be eliminated that there may be missing chemistry (item 4(d) above), the NAS update report indicates that major changes in our understanding of stratospheric chemistry are becoming less likely (Ref. 9, p. 19, see also quote in section II). Even without a complete understanding of all the chemistry, it is clear at this time that ozone is being depleted by reactions with chlorine in the stratosphere. As stated by the NASA workshop report, "* * * the detection and measurement of Cl and ClO, coupled with previous measurements of O(^{1}D) and with laboratory kinetic studies of reactions, $Cl+O_3 \rightarrow ClO+ClO+O \rightarrow Cl+O_2$, establishes that catalytic removal of O_3 by these reactions is [emphasis added] proceeding in the high stratosphere." (Ref. 3, p. 177.)

The Commissioner concludes that while all of the above are important reasons to continue a strong measurements research program, they are not valid reasons to halt reasonable preventive measures to protect our health and environment from impacts that may result should current model predictions be substantially correct.

(5) Diurnal chemistry—A comment stated that the time dependence of chemical reactions in the atmosphere due to diurnal effects is only approximated in 1-D models.

The Commissioner is aware that averaging techniques are used to approximate the effects of the sun's radiation on chemical reactions in the atmosphere. The NASA workshop report describes how these effects are accounted for in current models (Ref. 3, pp. 139–144). The report explains that time and cost do not permit the direct approach of integrating diffusion equations to properly reproduce essential diurnal effects, so "some form of diurnal averaging is necessary." (Ref. 3, p. 139.)

The Commissioner notes that the only measurements of diurnal effects to date are in close agreement with those obtained using present diurnal averaging techniques (Ref. 11). The Commissioner will continue to monitor the on-going efforts by NASA-sponsored scientists to improve these techniques.

(6) Limitations of one-dimensional (1-D) models—Several comments noted that one-dimensional models are being used to predict ozone depletion in a three-dimensional atmosphere. The comments suggested that two- and three-dimensional models are being developed which will more accurately describe the situation, and that regulation should be delayed until they are available.

As an overview, NASA states that: "In general, current evaluations of the relationship between model predictions and the response of the atmosphere rest on the degree of agreement between model calculations and concentrations in the current atmosphere." (Ref. 3, p. 193.) The extent of agreement between model predictions and field measurements is discussed above under item 9(a)(4).

The Commissioner is aware that there are problems inherent in the simplified approach of the 1-D model. "The one-dimensional (1-D) model is a particular simplification of the atmospheric radiative/chemical/dynamic system in which chemistry is treated in greater detail than radiation or dynamics." (Ref. 3, p. 133.) Latitudinal and seasonal dependencies of transport, temperature, and the solar flux are better described by multi-dimensional models. However, "* * * a generally applicable model of interactive RCD (radiation, chemistry, and dynamics) will not be available in the near future." (Ref. 3, p. 197.) NASA concludes that "The results of these models (1-D models) provide the best available estimate of the CFM effects on ozone that depends on the anticipated CFM-release scenario." (Ref. 3, p. 226.)

The Commissioner concludes that until more comprehensive multi-dimensional models are available, the 1-D model can and must be used as a predictive tool for assessing possible changes in the natural ozone content resulting from chlorofluorocarbon releases.

(b) Effects Resulting from Reduction and/or Redistribution of Stratospheric Ozone.

(1) Uncertainties in estimates of new cases of nonmelanoma skin cancer—A few comments questioned whether the relationship between nonmelanoma skin cancer and exposure to UV-B radiation has been well enough established to estimate increases in the incidence of this disease as a result of chlorofluorocarbon-induced increases in UV-B transmission to earth.

The Commissioner believes that the currently available scientific data support the existence of a causal relationship between UV-B exposure and the induction of nonmelanoma skin cancer. As the NAS report states: "For nonmelanomas three kinds of evidence—latitude dependence, body location, and occupational differences—all combine to point closely to exposure to the sun as a prime cause and to increased incidence as a quite certain consequence of increased DUV." (Ref. 1, p. 85.) The Commissioner recognizes that there are many uncertainties concerning the exact nature of this relationship and that attempts to quantify the effects must, of necessity, use certain assumptions. The increase in the estimate of ozone reduction from 7 percent to 16.8–18.8 percent also increases the estimate of the number of new cases of nonmelanoma skin cancer that could result from continued releases of chlorofluorocarbons at 1973 emission rates as calculated in FDA's environmental impact statement (Ref. 5, section 3.3.2). The uncertainties, assumptions, and ameliorating circumstances associated with making such an estimate are also discussed in FDA's environmental impact statement (Ref. 5, section 3.3.3).

The Commissioner concludes that "a quantitative estimate of impact (nonmelanoma skin cancer), even if uncertain by a factor of 2–4, is useful in order to assess whether the impact is potentially important or trivial." (Ref. 5, section 3.3.2.2.) The Commissioner also notes that, although "projections of melanoma cases and melanoma-related deaths cannot be made at this time, * * * both cases and deaths could be higher with a no action alternative than would occur if U.S. chlorofluoromethane emissions were restricted." (Ref. 5, section 4.3.)

Two comments suggested that changes in lifestyle may ameliorate human biological damage due to increased UV-B. The Commissioner has already responded to this point in the preamble to the final warning statement regulation (see the FEDERAL REGISTER of April 29, 1977 (42 FR 22023–22024)). Further discussion is also provided in FDA's environmental impact statement (Ref. 5, section 3.3.3).

(2) Uncertainties in the nature and magnitude of possible nonhuman biological and climatic impacts—Two comments pointed out the uncertainty involved in determining biological and climatic effects due to ozone depletion. They stated that the effects of UV-B on plant and animal life are little understood and that the potential for temperature changes and disruption of weather patterns remains unquantified. The comments conclude that these effects should not be used as a basis for regulating chlorofluorocarbon uses.

The Commissioner agrees that the magnitude and nature of the effects on biological systems and climate are uncertain. The Food and Drug Administration has already responded to comments on nonhuman biological effects from increased UV-B in a previous FEDERAL REGISTER document (see the FEDERAL REGISTER of April 29, 1977 (42 FR 22024–22025)). Additional discussion of these projected impacts, including the associated uncertainties and ameliorating circumstances, is given in FDA's environmental impact statement (Ref. 5, section 3.2). From

this document the following summary of potential impacts is provided: From basic photobiological knowledge, we can generalize that organisms are currently living in, and apparently coping with, a radiation field of damaging solar DUV.[1] The potential effects from increased UV-B to sensitive plant species include decreased photosynthesis, decreased rate of biomass accumulation and development, decreased fruit or grain yield, decreased reproductive ability, altered structure, altered competitive ability, and decreased resistance to other physical and chemical stresses. The potential effects on sensitive animal species include increased incidences of cancer, photokeratitis and cataracts, and altered competitive ability.

If nonhuman biological effects occur, the consequences could be important. Consequently, it is warranted to consider this risk along with other effects in assessing regulatory action, notwithstanding the gaps in knowledge about these effects. Since regulatory action is justified because of the other risks from chlorofluorocarbons, the Commissioner need not decide now if the risks to nonhuman organisms alone would warrant the initiation of a phaseout or some other type of regulatory action.

Two comments specifically questioned the use of possible impacts of chlorofluorocarbons on climate as a basis for taking the proposed action. In support of this position, the following quote from the NAS report was cited:

> The direct climatic effect, which seems most likely to be serious, is immediate (is not delayed for the CFM's to reach the stratosphere) and shows no overshoot (the effects of current release show more rapidly). It is probably not a concern at present levels of CFM accumulation. Thus, delay in decision is even more reasonable, as far as direct climatic effects go, than for the effects of ozone reduction. (Ref. 1, p. 13.)

The Commissioner responded to a similar comment in the final regulation to require warning labels on containers using chlorofluorocarbon propellants (see the FEDERAL REGISTER of April 29, 1977 (42 FR 22025)). The Commissioner points out that the direct climate effects could be immediate or delayed. The NAS report further explains the direct climatic effects as follows:

> If CFM use and release were to continue at a constant rate the amount of direct climatic effect would also flatten out, approaching a steady state, again reaching half of this value in about 50 years. The increase of infrared absorption and emission would similarly reach half of its ultimate value in about 50 years. Resulting climatic effects might be further delayed because of slowness in response in the climatic mechanism. (Ref. 1, pp. 4-5.)

The direct climatic effect described in the first quote (Ref. 1, p. 13) must refer to the physical process of increased absorption and emission of infrared radiation by chlorofluorocarbons. The process would occur immediately upon release of chlorofluorocarbons into the atmosphere. As described in the second quote (Ref. 1, pp. 4-5), the actual climatic effects resulting from the increased absorption and emission of infrared radiation by chlorofluorocarbons may occur immediately and increase in magnitude as the concentrations of chlorofluorocarbons in the atmosphere increase (assuming continuous release), or they may be delayed due to a lag time between the physical process (absorption and emission of infrared radiation) and the event (observed effects on climate). The Commissioner further notes that even if the climatic effects resulting from chlorofluorocarbon release are immediate, the source of the observed effects may not be recognized as chlorofluorocarbons for a considerable period of time.

Regarding the magnitude of possible direct climatic effects, the NAS states: "The estimated climatic effects of CFM releases * * * are sufficiently large that continued release of CFM's, at their 1973 rates, must be recognized now as potentially serious." (Ref. 1, p. 65.)

The response to the use of possible direct and indirect climatic effects as a basis for regulatory action is still the following:

> The Commissioner believes the critical importance of climatic effects warrants their being taken into account in assessing regulatory action, notwithstanding the gaps in knowledge about climate. Since regulatory action is justified because of the other risks from chlorofluorocarbons, the Commissioner need not decide now if the climatic risks alone would warrant the initiation of a phaseout or some other type of regulatory action (FEDERAL REGISTER of April 29, 1977 (42 FR 22025).)

The Commissioner agrees that much research is needed to provide a better understanding of the possible nonhuman biological and climatic impacts that may result from perturbations in stratospheric ozone. The Biological and Climatic Effects Research program sponsored by EPA is addressing this area of potential risk.

10. Several comments requested that regulation be delayed until actual ozone measurements indicate that column ozone is decreasing. The point is made that this would be a good test of the validity of present models. Dr. W. J. Hill et al. (Refs. 12, 13) have statistically analyzed past ozone measurement data and determined that an abnormal global ozone change of 0.28 percent total deviation from historical patterns of ozone trends could be detected with present monitoring capabilities. A 1.56 percent early warning (the result of a 0.26 deviation per year for 6 years) could limit maximum reversible depletion to 2.3 percent, if the cause was due to chlorofluorocarbons and all global chlorofluorocarbon emissions were eliminated at the time the 1.56 percent deviation in column ozone is detected.

In January 1977, the NASA workshop concluded that "* * * it is clear that a larger data set (based on more precise observational techniques) than is currently available is needed to verify the rate of ozone destruction by CFM's postulated by the models discussed in this document." (Ref. 3, p. 87). In July 1977, a NASA-sponsored meeting was held in Boulder, Colo., to discuss the practical application of ozone trend detection systems. There was no agreement at this meeting that an abnormal ozone trend of the magnitude described above could be detected if it were to occur. The major criticism of the Hill early warning system was that he had not adequately accounted for the limits in the accuracy of ozone monitoring instruments.

The Commissioner notes that the Hill system, even in a perfected state, would only provide an early warning for abnormal deviations in total column ozone. Reliance on this system would leave the public unprotected against the possible climatic impacts that might occur as a result of chlorofluorocarbon-induced alterations in the distribution of stratospheric ozone, even in the absence of detectible variations in column ozone.

The Commissioner will continue to monitor the attempts to improve upon this ozone trend detection system but concludes that it is not yet refined enough to rely upon for protection of the public against possible chlorofluorocarbon-induced reductions and redistributions in stratospheric ozone.

11. Several comments specifically requested that FDA delay the effective date for the phaseout of nonessential chlorofluorocarbon propellants until December 1980. The following reasons were cited for the requested delay: (a) "The impact of the world of waiting a couple of years before deciding whether or not to regulate the uses and releases of F-11 and F-12 is small although we are uncertain just how small." (Ref. 1, p. 9); (b) there has been a 40 percent drop in the sales of chlorofluorocarbon propellants since 1974, and (c) a definitive answer on the health hazards associated with potential replacement propellants, hydrochlorofluorocarbons 22 and 142B, may not be available until late 1979.

The Commissioner has already responded to item 11(a) above in the Scientific Overview, Section II in the preamble to this regulation.

[1] DUV: Biologically harmful ultraviolet radiation; similar to UV-B.

The manufacturers of chlorofluorocarbon propellants have reported a 40 percent drop in sales over the past 2 to 3 years (item 11(b) above). Estimates of potential effects resulting from the use and release of chlorofluorocarbons have been based on 1973 and 1975 production and emissions data. Comments contend that a delay of 12-18 months in the phaseout regulation is now possible without any increase in magnitude of the estimates of potential health and environmental impacts forming the basis of the regulatory action.

It is the Commissioner's goal to reduce the risks associated with chlorofluorocarbon emissions from nonessential aerosol propellant uses to the greatest extent possible and as soon as possible, allowing time for an orderly phaseout. Additionally, the Commissioner notes that on the basis of new scientific data, NASA recently has concluded that the current best estimate of ultimate ozone depletion as a result of chlorofluorocarbon emissions at 1975 release rates must be revised upward to 10.8-16.5 percent (Ref. 3, pp. 189-195). The new estimate represents approximately a two-fold increase over the NAS estimate of 7 percent ultimate ozone depletion. This increase in the estimate of chlorofluorocarbon effects on stratospheric ozone more than offsets the decrease in such effects that would result from the reported reduction in U.S. emissions.

The Commissioner acknowledges the efforts of industry to encourage conversions to nonchlorofluorocarbon-propelled mechanisms of product delivery, particularly in the form of public advertising. This advertising campaign, along with the visibility given by the press to the potential impacts resulting from chlorofluorocarbon emissions, has undoubtedly been responsible for most of the 40 percent drop in sales. A consumer response of this magnitude is viewed by the Commissioner as a strong indicator of public support for the regulation.

Furthermore, the drop in U.S. sales of chlorofluorocarbons for use as aerosol propellants has not markedly reduced world-wide production of these compounds (Ref. 9, p. 17). World-wide reduction of chlorofluorocarbon emissions is necessary to minimize the associated risks and cannot be achieved unless the United States takes a strong action to reduce its own production and release of chlorofluorocarbons. For all these reasons, the Commissioner concludes that an extension of the effective date for the regulations cannot be justified on the basis of reduced sales.

The third reason (item 11(c) above) given by those requesting a delay in the effective date of the phaseout until December 1980 was that the necessary toxicity testing of alternative propellants, hydrochlorofluorocarbons 22 and 142B, has not yet been completed. Both of these hydrochlorofluorocarbons have been found to be mutagenic in a bacterial bioassay test (the Ames test). Based on these results, DuPont and Allied Chemical, the major flurocarbon producers, have recommended that neither hydrochlorofluorocarbon be used as an aerosol propellant for consumer products until toxicity testing indicates that they are safe.

The present action is being taken to protect the public health and the environment from the possible adverse effects resulting from ozone depletion. The fact that certain potential replacement propellants are not yet adequately tested is incidental. There are nonpropellant alternatives available and the uses of chlorofluorocarbons affected by this regulation are nonessential. The Commissioner cannot justify the possibility of further chlorofluorocarbon-induced alterations in stratospheric ozone while waiting for the development of alternative propellants for nonessential aerosol uses (see also the FEDERAL REGISTER of April 29, 1977 and May 13, 1977 (42 FR 22027 and 24539, respectively)).

B. *Additional responses to requests for information.* The Commissioner notes that he has received a few additional comments in response to FDA's requests for information in specific scientific areas (see the FEDERAL REGISTER of November 26, 1976, and May 13, 1977 (41 FR 52071 and 42 FR 24539).)

12. One comment attempted to put into perspective the uncertainties associated with currently used methods for estimating tropospheric hydroxyl radical (OH) concentrations, including that used by Singh (ref. 14). Apparently the accuracy of the measurements used to calculate OH concentrations is often not accounted for in indirect estimates of tropospheric OH levels. The comment concludes that until direct measurements are available or until consistent estimates are obtained by several indirect methods such as that of Singh (ref. 14), estimates of tropospheric lifetimes for hydrochlorofluorocarbons based on OH reactions cannot be established with confidence.

The submission provides helpful information for understanding the uncertainties associated with indirect methods of estimating tropospheric OH concentrations. The Commissioner will await additional verification of existing estimates before formulating definitive conclusions about the potential impacts associated with the release of halocarbons which react more readily with OH in the troposphere than do chlorofluorocarbons, e.g., the hydrochlorofluorocarbons and methyl chloroform.

13. A scientist submitted information on the results of laboratory measurements of the ultraviolet absorption characteristics of several brominated compounds. He reports that $CBrF_3$ (F-13B1), $BrClF_2$ (F-12B1) and $CBrF_2CBrF_2$ (F-114B2) will not photodissociate in the troposphere. All available information therefore indicates that the perhalobromoalkanes are generally comparable in stratospheric hazard to the chlorofluorocarbons. The same investigator finds that iodocarbons are subject to tropospheric photodissociation and, therefore, represent less of a hazard to stratospheric ozone with respect to chlorofluorocarbons.

The Commissioner notes that to his knowledge there are no perhalobromoalkanes being used as propellants in FDA-regulated products and therefore there is no need to consider regulation of these compounds at this time. Brominated fluorocarbons are currently used in products subject to EPA jurisdiction, e.g., fire extinguishers. EPA is considering these uses in making regulatory decisions on nonpropellant, fully halogenated halocarbon emissions (see the FEDERAL REGISTER of September 22, 1977 (42 FR 47863)).

IV. LEGAL ISSUES

14. Several comments maintained that because of the exemptions in section 3 of the Toxic Substances Control Act, EPA does not have authority under that act to prohibit the manufacture or manufacture for export of chlorofluorocarbon propellants that might ultimately be used in a food, food additive, drug, cosmetic, or device. One comment requested FDA to withdraw the statement in the preamble to the proposed FDA rule that exported foods, cosmetics, and other articles were subject to the Toxic Substances Control Act to the extent they were exempt from the Federal Food, Drug, and Cosmetic Act pursuant to section 801(d) of the Federal Food, Drug, and Cosmetic Act.

The comments deal primarily with EPA's authority under the Toxic Substances Control Act, and EPA plans to respond to these comments. EPA intends to make some changes in its regulation with respect to the matters dealt with in the comments. In view of the responses and changes being made by EPA, the Commissioner does not believe it necessary to make any additional responses to the comments, or to state a final position at this time on the applicability of the Toxic Substances Control Act to exported foods, cosmetics, and other articles to which the Federal Food, Drug, and Cosmetic Act is inapplicable.

15. One comment urges FDA to prohibit subsidiaries of U.S. corporations operating overseas from manufacturing or selling chlorofluorocarbons for aerosol uses.

FDA has no statutory authority to take the action sought in the comment.

V. Economic Issues

A. Impact on costs and prices. 16. A comment by a trade association asserted that most of the economic impact of the phaseout will fall on the marketing industry.

The Commissioner agrees with this assertion. The agency's economic impact statement (ref. 6) contains estimates that confirm this impact on marketers.

17. Two comments indicated that the shortage of capacity to produce pumps will hinder a conversion to mechanical delivery systems by the April 1979 phaseout date. The estimate of current pump production is about 300 million units per year, with a possibility of doubling this output each year. Even with this rapid expansion, it is asserted that there will be a shortage of pumps for the near future.

The Commissioner agrees that, in the short-run, the demand for pumps as an alternative to chlorofluorocarbon aerosols may exceed the production of pumps. The economic impact statement prepared by the agency (ref. 6) considered this supply bottleneck as one cause of lost sales by marketers. Although it is difficult to predict what percentage of lost sales will be caused by supply constraints, the agency estimated that, in the first 2 years following the phaseout, sales lost due to supply constraints will exceed those lost for other reasons and will be great enough to cause a major economic impact, i.e., losses greater than $100 million annually. After that time, production of pumps should be sufficient to meet demand.

As previously mentioned in comment 11, chlorofluorocarbon manufacturers have recently reported a 40 percent drop in their sales of chlorofluorocarbon propellants since 1974. This could mean that the anticipated supply shortage of mechanical devices such as pumps may also be diminished by as much as 40 percent. The International Research and Technology Corp. study (ref. 15) estimated lost sales at $199 million for an 18-month phaseout period. If it is assumed that 50 percent of these losses would be caused by supply constraints, bottlenecks will cost at least $100 million in sales. Use of the chlorofluorocarbon propellant sales figures could reduce the sales loss due to shortages of mechanical delivery systems to as low as $60 million for an 18-month phaseout. The Commissioner notes, however, that the agency does not have firsthand knowledge of the most recent data and, therefore, cannot say with certainty that the reduction in use of chlorofluorocarbons as propellants already achieved would result in a 40 percent cut in the sales loss due to shortages. To the extent that conversions to non-chlorofluorocarbon-propelled products have already been made by industry, a phaseout by the effective dates will be less costly to achieve.

One possible solution to the shortage of pumps is to use refillable pump containers. Thus, one pump could propel two or three bottles of hair spray, for example. Until pump production is increased enough to satisfy demand, this strategy could keep consumer prices down by eliminating the purchase of a pump each time a product needing a spray propellant is bought; at the same time manufacturers of these products maintain their sales.

18. One comment expressed concern that if regulatory efforts are applied too early, before satisfactory alternatives are identified for all aerosol uses of chlorofluorocarbons, the consumer may lose his "right to free choice" in the aerosol market. It was further stated that no recognition was given to the intangible social costs to consumers who cannot find an acceptable alternative to chlorofluorocarbon aerosols or who cannot buy a substitute because of supply shortages.

The Commissioner recognizes that the phaseout may deprive the consumer of the choice of an aerosol or a particular type of aerosol delivery system for certain products and that this choice and variety in the marketplace are desirable. However, as the Commissioner has stated in the FEDERAL REGISTER of April 29, 1977 (42 FR 22030), additional time for toxicity testing of effective alternative propellants provides no guarantee that any will be found to be safe and thus available for consumer use. The agency attempted to measure the social cost to consumers by identifying the upper limit of $228 million in lost sales (ref. 6). Although this is a loss to industry, it is also a proxy for the loss to consumers who can no longer buy a product that is acceptable to them. The $228 million is, in a crude sense, a measurement of the consumers' willingness to pay for products propelled by chlorofluorocarbons. This loss is expected to diminish over time both to industry and to consumers as better substitutes, and as supplies of essential materials increase. The Commissioner believes substantial progress has been made in these areas as indicated by the degree of substitution already made by industry (see comments 11 and 17), and it can be assumed that this indicates a willingness of consumers to use alternative products.

Furthermore, this is a case in which the adverse consequences of the choice do not fall solely on the individual consumer. A substantial interest exists in protecting the "right to free choice" of the individual who does not want to be exposed to the potential health and environmental impacts associated with the continued use of nonessential chlorofluorocarbon propellants.

19. Four comments stated that consumer costs may increase, not decrease as the agency estimates, as use of chlorofluorocarbons in aerosols is phased out. A chemical manufacturer elaborated on this point by suggesting that, instead of passing along savings on the cost of alternative propellants and mechanical substitutes, companies may hold their prices constant or even increase them to recoup some of the costs of the phaseout.

The Commissioner believes that the phaseout may result in somewhat lower consumer prices as manufacturers replace chlorofluorocarbons with less expensive propellants and mechanical applicators. The structure of the cosmetic industry will make it difficult for producers to maintain or increase their prices because the large number of firms in this industry create both price and product competition. Any company increasing prices is expected to face a loss of its market share to competing companies that pass along cost savings to the consumer. As the agency recognized in its economic impact statement (ref. 6), it is this competition in connection with less expensive substitutes that will allow consumers to receive some savings from the phaseout. If, however, the savings from the cheaper alternative materials are not passed on to the consumer but retained by the manufacturers to offset the cost of the phaseout, the industry will have a smaller loss as the consumer has a smaller gain. Thus the overall economic impact would be about the same magnitude.

The Commissioner concurs that chemical manufacturers will not be able to pass through the additional costs of the phaseout to its aerosol customers. Instead, the chemical producers will attempt to recoup their losses due to the phaseout by increasing chemical prices to their nonaerosol customers.

20. Two comments criticize the agency's estimate of the cost of the phaseout because certain costs to the government have not been considered. One example the comments give is that tax revenues will fall as the aerosol industry loses sales and workers are laid off due to the agency action.

The Commissioner agrees that there may be some decrease in tax revenues because of the phaseout and resulting loss of sales and employment. However, as consumers purchase other goods, either substitutes for the aerosol products or entirely different goods bought with the money not used for aerosols, new business activity and tax revenues are generated. Hence, the net tax loss caused by the phaseout of chlorofluorocarbon aerosols, although difficult to quantify, is expected to be an insignificant portion of tax collections nationally.

21. Another comment asked if the agency had considered putting a Federal tax on chlorofluorocarbon-propelled aerosol cans, presumably as a means to reduce the sale and use of the products.

The Commissioner is doubtful that a tax on chlorofluorocarbon-propelled aerosol containers would provide sufficient incentive to reduce significantly the sale and use of these products. Legislative action would be needed to impose such a tax. Lastly, in this case, it is inappropriate to allow those willing to pay more to determine the extent of risk that all must bear.

B. *Impact on employment.* 22. Comments by a chemical manufacturer criticized the agency for failing to quantify the loss of jobs in the economic impact statement. The company also felt that inadequate consideration was given to employment losses in the chemical and marketing industries.

The impact of this phaseout on employment was fully considered in the economic impact statement. The number of jobs lost was estimated as approximately 1,700 for an 18-month phaseout period for chlorofluorocarbon aerosols, with some of the loss offset by an increase in employment in nonaerosol production.

The employment loss will be concentrated in the filler, valve, and container industry because the chemical and marketing sectors of the aerosol manufacturing process can shift more easily into production of other products. The chemical industry will move into new products, including alternatives to chlorofluorocarbons, and the marketers will increase their emphasis on such things as mechanically delivered cosmetics. There may be some job losses in these industries, but it is reasonable to assume that most of the employment impact will be felt in the container industry, which is more closely tied to the use of chlorofluorocarbons as propellants.

23. Two trade associations commented that the phaseout of chlorofluorocarbon aerosols will lead to higher unemployment and that the impact of the ban would be mitigated if the compliance period were longer. Both noted that a longer phaseout period that allowed hydrochlorofluorocarbons 22 and 142B as possible alternatives would reduce the job and industry sales losses.

A longer phaseout period would diminish somewhat the job losses from the ban, as the analysis in the economic impact statement (Ref. 6) has indicated. The economic impact would probably be reduced if hydrochlorofluorocarbons 22 and 142B were available as propellants. The reasons for not postponing the effective dates of this regulation to wait for research results on alternative products have been stated in the response to comments 11 and 48. Since hydrochlorofluorocarbons 22 and 142B are not currently a viable alternative to chlorofluorocarbons, it does not appear to be meaningful to discuss what the economic advantages and disadvantages of using these substances will be.

C. *Impact on competition.* 24. Two comments urged a delay in the proposed ban to lessen the competitive impact both on the filler industry and on the aerosol marketers. The comments indicated that the filler industry has many small companies that receive the bulk of their business from a limited number of products. These small companies will have difficulty in raising capital to convert their equipment from chlorofluorocarbon to hydrocarbon systems. The comments also indicated concern that a relatively short phaseout could lead to a shift in the market shares in the marketing industry because one firm may move more quickly to find an alternative and thus attract additional customers.

The Commissioner acknowledges that some competitive impact may be caused by the phaseout of chlorofluorocarbon propellants. The economic impact statement prepared by the agency noted that, although all segments of the aerosol industry were examined for an anticompetitive effect of the agency's action, the brunt of the impact fell on the filler industry.

Within the filler industry, there are two kinds of operations. Some filler companies are affiliated with cosmetic firms, and they will probably be able to convert from chlorofluorocarbon to hydrocarbon and carbon dioxide propellants without much difficulty. The small filler firms that operate under contracts may have difficulties in securing capital to convert their lines to alternative propellants. One real cost of the phaseout is that some of these companies may go out of business. It is unclear, however, if extending the phaseout period would significantly help the filler companies to stay in business.

The Commissioner disagrees with the comments on the anticompetitive impact the phaseout will have on the aerosol marketing industry. Most products now on the market have a mechanical or nonchlorofluorocarbon propellant alternative to aerosols. As the effective date of the regulation approaches, marketers should be able to shift more of their product line into these alternatives. If one company introduces a new propellant that is more acceptable to consumers, there is no reason to believe that this will be anticompetitive.

VI. Essentiality Issues

The criteria used by the agency to determine the essentiality of chlorofluorocarbon propellant uses are given in § 2.125(f) of this regulation.

A. *Food and cosmetics.* 25. One comment took the form of a petition requesting FDA to specify that dry shampoos consisting of starch propelled by chlorofluorocarbons be exempt from the regulation. These shampoos were claimed to be especially beneficial to people unable to wash themselves, i.e., many hospitalized patients and outpatients. It is claimed that chlorofluorocarbon propellants 11 and 12 are essential ingredients in this product and are used in such small amounts that only an insignificant danger is presented to the environment. The firm states that "nonaerosol, dry shampoo substitutes are, by comparison, ineffective and undesirable." The firm claims that the density of the propellant 11/12 blend "enables it to hold the starch particles in uniform suspension (after gentle shaking) during the normal consumer application process." Testimony obtained in a 1971 survey conducted among registered nurses was submitted which indicated a preference among this group for the instant shampoo product. The firm concludes by stating that they "believe that measured against the loss of patient morale and the disruptive effect this may have on the therapeutic regimen, particularly during prolonged hospitalization or chronic illness, the release of chlorofluorocarbons by these products is warranted."

The Commissioner concludes that the petitioner's contentions do not constitute sufficient grounds for exemption from this ban on chlorofluorocarbon propellants. Although the product may provide some benefit, the claim that other propellant/solvent systems do not provide the propellant's suspending property is not documented. Other propellant/solvent systems capable of delivering the starch spray in aerosol form are available, as are manual pump spray delivery systems.

26. Another comment was received from a manufacturer of antiseptic lubricants for food processing machinery. It states that the application of lubricants by aerosols containing chlorofluorocarbon propellants is more uniform than manual application. It further states that this form of application is more sanitary than "the old fashioned method of spreading lubricants by hand." The firm believes that "no satisfactory substitute for chlorofluorocarbon propellants in this application has been developed to date." The firm states that it "believes that use of chlorofluorocarbon propellants in such products provide a public health benefit not obtainable from alternative means of delivery * * *." This statement is presented as a belief and is unaccompanied by any documentation to support the claim.

The Commissioner notes that alternative solvent and delivery systems

are available to apply "sterile" lubricants to food-processing machinery. For example, pump spray applications, grease gun applicators, or metered liquid delivery systems may be used in place of self-pressurized containers. While the Commissioner does not deny that application via self-pressurized containers may be somewhat more convenient, there is no submitted evidence to support a conclusion that delivery by self-pressurized containers provides a substantial public benefit not available in other forms of delivery. Accordingly, the Commissioner is denying the request for exemption of these products from the prohibition on the use of chlorofluorocarbon propellants.

27. Six comments were received expressing concern about the effect of this action on the use of chlorofluorocarbons as blowing agents in the manufacture of polystyrene foam sheets.

This regulation does not relate to nonpropellant uses of chlorofluorocarbons and, therefore, the utilization of these compounds as blowing agents in the manufacture of polystyrene foam sheets will not be affected by this regulation. A public meeting sponsored by EPA, FDA, and CPSC was held on October 25 through 27, 1977, for the purpose of collecting information on nonpropellant uses of chlorofluorocarbons. Another joint public meeting on nonpropellant uses of chlorofluorocarbons is scheduled for February 21 through 24, 1978 (see notices in the FEDERAL REGISTER of January 13, 1978 (43 FR 1997)).

28. A citizen petition from the Michigan Department of Public Health was received requesting that the Commissioner ban foods and cosmetics containing chlorofluorocarbon compounds because of the danger these pose to the ozone layer.

The petition supports the action being taken in this order.

B. *Drugs.* 29. One comment requested that, for those drug products containing a chlorofluorocarbon for an essential use not currently covered by a new drug application (NDA), the regulation should specify that an abbreviated NDA must be submitted. The comment stated that there is no reason to require full NDA's for over-the-counter (OTC) products exempted from the phaseout regulation while requiring only abbreviated NDA's for prescription drug products covered by a DESI notice.

The Commissioner agrees that a full NDA is not needed for those few exempted OTC drug products that contain a chlorofluorocarbon for an essential use not currently covered by approved NDA's. These products include some metered-dose adrenergic bronchodilator drug products for oral inhalation and some contraceptive vaginal foams. The regulation has been revised to indicate that an abbreviated NDA may be submitted. Because of the unusual delivery system, however, the regulation will require that full manufacturing procedures be submitted as part of the abbreviated NDA.

30. One comment urged that the use of chlorofluorocarbons as propellants in all OTC medicines be considered essential uses, exempt from the phaseout regulations.

The Commissioner disagrees with this comment and concludes that the test for an essential use of a chlorofluorocarbon should remain the same as in the proposed regulation of May 13, 1977 (42 FR 24538). Under the suggested criteria, i.e., exempting any OTC medicine in which a chlorofluorocarbon is used as a propellant for more than consumer convenience, it would not even be necessary to show that whatever benefit was gained by using an aerosol product could not also be gained by using a technically feasible alternative.

31. One comment said that the five product classifications listed in proposed § 2.125(e) (21 CFR 2.125(e)) are inadequate and should be amended to include additional classes of drug products. The comment further discussed a product, currently undergoing human clinical testing, that uses a chlorofluorocarbon to propel a topical anesthetic that anesthetizes the endotracheal mucous membranes prior to endotracheal intubation. The comment said that as soon as the necessary information was collected, it would be submitted as a petition requesting FDA to include such a product on a list of essential uses of chlorofluorocarbons.

The Commissioner recognizes that the list of essential uses of chlorofluorocarbons contained in proposed § 2.125(e) may not be complete and for this reason has included in § 2.125(f) a statement pertaining to the submission of petitions to amend the list of essential uses. The Commissioner encourages interested persons to use this provision and submit such petitions with the necessary supporting data.

32. One comment requested that a product used as a powdered wound dressing, containing a chlorofluorocarbon as the propellant, be declared an essential product. The comment pointed out that: (a) The chlorofluorocarbon propellant used is the only existing propellant capable of dispensing the material from an aerosol container; (b) although the product could be dispensed from a nonaerosolized container, the aerosol use offers certain advantages, such as prevention of contamination of the product and uniform application to the wound; and (c) since extremely small quantities of the product are required even for the treatment of substantial wounds, the amount of chlorofluorocarbon released to the atmosphere would be negligible.

Although the comment said that a chlorofluorocarbon is the only existing aerosol propellant capable of dispensing this material from an aerosol container, no information was supplied indicating what other propellants were tried and why they were not suitable. To address the potential contamination problem, the Commissioner believes that a nonaerosol pump could be used, if the product were reformulated to include a bacterial preservative. While the aerosol may provide a more uniform application of the product, the comment did not establish that the size of the particles or the quantity of the drug dispensed was of a critical nature with this product. Because of these factors, along with the fact that the product can be dispensed from nonaerosolized containers, the Commissioner rejects this comment.

33. One comment requested that a surgical scrub product containing 3 percent hexachlorophene in an aerosol container and using a chlorofluorocarbon as the propellant be declared an essential product. The comment restated the provisions of the chlorofluorocarbon proposal, but did not contain any justification for finding the use of chlorofluorocarbon in this product an essential use.

The Commissioner cannot accept this comment. He is not aware of any reason to support a finding that this product provides a benefit unobtainable without the use of chlorofluorocarbon. In fact, even the comment acknowledged that the product can be dispensed in other than aerosol form.

34. One comment requested that a metered-dose ergotamine drug product, employing a chlorofluorocarbon as the propellant, be listed as an essential use of chlorofluorocarbons. The comment contained a detailed discussion supporting the position that there is a lack of any technically feasible alternative to the use of a chlorofluorocarbon in metered-dose drug products. This same information had previously been submitted in response to the notice of intent to propose rules banning nonessential uses of chlorofluorocarbons and request for information published in the FEDERAL REGISTER of November 26, 1976. The comment also argued that the product provides a substantial health benefit that would be unobtainable without the use of a chlorofluorocarbon. Data were submitted to show that the aerosol form of ergotamine had the same speed of action as an intramuscular injection of the same dose. Another advantage of the aerosol form, argued the comment, is that it can be used by the migraine patient who is experiencing nausea and has difficulty in swallowing a tablet and keeping it down.

The comment also stated that since the container consists of only 7 grams and contains a meter spray valve, the use of chlorofluorocarbons in this product does not involve a significant release of chlorofluorocarbons into the atmosphere.

As indicated in comment 45 of the final regulations requiring a warning statement on certain chlorofluorocarbon-containing products published in the FEDERAL REGISTER of April 29, 1977 (42 FR 22029), the Commissioner recognizes the importance of chlorofluorocarbons in providing effective metered doses for use in inhalation therapy for certain specific diseases. He agrees with the comment that the use of ergotamine tartrate by inhalation provides a unique benefit to the migraine patient which is not available in other forms of self-medication and has amended § 2.125(e) to include metered-dose ergotamine tartrate drug products for oral inhalation.

35. One comment requested that an aerosol product containing lidocaine, employing a chlorofluorocarbon as the propellant, in a metered-dose container, be listed as an essential use of chlorofluorocarbon. The product is used for the production of topical anesthesia of gingival and oral mucous membranes. The comment explained why other propellants are not satisfactory, either because of their potential toxicity when inhaled, or because of the unavailability of an acceptable metered aerosol delivery valve for such other propellants. It was also argued that the aerosol form of the product provides unique health benefits not achievable with alternative dosage forms. The comment further said that the use does not involve a significant release of chlorofluorocarbons into the atmosphere in that it has limited distribution to dentists and that a maximum of 120 milligrams (two actuations of the metered dose valve) of chlorofluorocarbon would be released per patient.

The Commissioner recognizes the importance of using a metered-dose aerosol for delivering lidocaine to the oral cavity, if the product is to be administered by the aerosol route. If a nonmetered aerosol container were used, the dose could not be controlled and serious undesirable systemic side effects could be produced. Although the comment explained why an ointment product is not a suitable alternative delivery system, it did not discuss why an injectable lidocaine product, or another delivery system such as use of a cotton swab to apply the drug product, could not be used in its place. Therefore, the Commissioner is not accepting this comment. Of course, a petition may be submitted in accordance with § 2.125(f) giving the reasons why other delivery systems are not acceptable.

36. One comment requested that a benzoin spray, used as a skin protectant and as a skin antiseptic, be declared an essential use of chlorofluorocarbon. The comment included the labeling for the product, but failed to include any other supporting data.

The Commissioner cannot accept this comment. Although the intended use of the product was described in the labeling, the comment did not discuss the points set forth in the preamble to the proposed regulation (see the FEDERAL REGISTER of May 13, 1977 (42 FR 24538)) as necessary to justify an essential use of a chlorofluorocarbon.

37. One comment requested that a self-powered atomizer, used to propel anesthetics into the laryngotracheal area prior to endotracheal intubation, be declared an essential chlorofluorocarbon use. Again, other than a picture and description of the product, no supporting data were included.

As above, the Commissioner cannot accept this comment because of the lack of justification in support of the essentiality claim.

This comment, however, brought to the Commissioner's attention another type of chlorofluorocarbon propellant system, i.e., a container of chlorofluorocarbon that is used to propel the contents of a different container when the two containers are attached together.

It was the Commissioner's intent to make all nonessential propellant uses of chlorofluorocarbon in FDA-regulated products subject to this regulation. The Commissioner has previously explained that under the agency's definition of "propellant," a chlorofluorocarbon is not considered a propellant if the pressurized container contains only chlorofluorocarbons or only gases (see the FEDERAL REGISTER of April 29, 1977 (42 FR 22018)). This statement was made to explain the intended effect of the definition on pressurized cylinders containing chlorofluorocarbons for nonpropellant purposes. There was no intent to exclude from coverage products using chlorofluorocarbons as a propellant to expel material from a separate container. If such products were exempt, it might lead to the development of new products using chlorofluorocarbon propellants in this form. The definition of propellant has been revised to indicate clearly that the regulation applies to all products in which a chlorofluorocarbon is used as a propellant whether or not the propellant is in the same or a separate container from the material propelled. If the propellant is in a separate container, that container would be the self-pressurized container subject to the restrictions in § 2.125(e).

38. Several comments requested that specific drug products containing one or more chlorofluorocarbons as an active ingredient be exempt from the phaseout regulations. The comment alleged that chlorofluorocarbons are active ingredients because they produce a vapocoolant effect which, as a skin refrigerant, is intended to relieve muscle pain. Three of the products consisted of 100 percent chlorofluorocarbons, one product contained 83 percent dichlorotetrafluoroethane and 17 percent ethyl chloride, and another product contained two chlorofluorocarbons as well as menthol, methyl salicylate, camphor, and isopropyl alcohol. These comments stated that no other propellant system can provide the vapocoolant effect produced by the chlorofluorocarbon and that the amount of chlorofluorocarbon being released is not substantial.

In proposed § 2.125(a)(2) the term "propellant" was defined as "a liquefied or compressed gas that is used in whole or in part to expel from a self-pressurized container liquid or solid material different from the propellant * * *." Because several of the products referred to in these comments consist entirely of chlorofluorocarbons not intended for use as a propellant, they are not subject to this regulation. The final rule to require a warning statement discusses the reasons for limiting the present action to propellant uses. The nonpropellant products will be the subject of regulatory considerations on nonpropellant uses of chlorofluorocarbons.

With respect to the product containing a chlorofluorocarbon and ethyl chloride, the compressed ethyl chloride is not dependent upon the chlorofluorocarbon to be expelled from the container, but acts as a propellant itself. The chlorofluorocarbon is not used to expel a liquid or solid from the container, but is present as an active ingredient. Therefore, this product is also exempt from this regulation but will be subject to any regulation applicable to nonpropellant uses of chlorofluorocarbons when and if they are published.

The product that contains two chlorofluorocarbons for their vapocoolant effect, along with several other nonpropellant ingredients, clearly falls within this regulation since the chlorofluorocarbons act as propellants of liquid or solid material. The propellant has other functions, but many propellants have dual functions. As previously explained in the final rule to require a warning statement, if all propellants with dual functions were excluded many products might be excluded, or might claim to be excluded. Since FDA regulates most aerosol uses of chlorofluorocarbons, if the scope of its regulation were narrowed or uncertain, the regulatory purpose of reducing nonessential uses could be significantly hindered. Thus, this products is subject to the regulation because of the propellant use of the chlorofluorocarbon.

The Commissioner, however, cannot accept the comment that declares this use an essential use of a chlorofluorocarbon. Neither this product, which is an OTC product, nor the other products containing a chlorofluorocarbon as an active ingredient, which are prescription products not the subject of a new drug application, previously have been reviewed for safety and effectiveness. Furthermore, the submission did not provide data to show that the product is effective to achieve its claimed benefit or to show it is safe. A submission indicated that the product could be sold in a liquid concentrate form. The aerosol form was claimed to be more convenient and effective, but the only support cited was anecdotal. A determination that the chlorofluorocarbon in these products is for an essential use obviously cannot be made until it is found out whether the products are safe and effective as well as safe to achieve the benefit claimed to be essential.

The one product containing a chlorofluorocarbon as an active ingredient that is subject to this regulation will, upon the effective date, be a new drug in view of the provision of § 2.125(c). This section says that any drug product in a self-pressurized container that contains a chlorofluorocarbon propellant is a new drug and is adulterated and/or misbranded unless specifically exempted by § 2.125(e). As stated previously, this product cannot now be listed in § 2.125(e). Therefore, if the manufacturer wishes to continue marketing this drug product after the effective date, a new drug application in the format specified in § 314.1(c)(2) (21 CFR 314.1(c)(2)) should be submitted as soon as possible, but not later than June 15, 1978. If the new drug application is approved, the firm must then submit a petition in accordance with § 2.125(f) to specify that this use of a chlorofluorocarbon is an essential use. The Food and Drug Administration will review both the NDA and the petition as quickly as possible.

Although the other products containing chlorofluorocarbons for nonpropellant uses are not subject to this regulation, these other products will be subject to any future regulation on nonpropellant uses of chlorofluorocarbons. To be considered for exemption as an essential product from a regulation on nonpropellant uses, the firm preparing the drug product will be required to establish that the product is safe and effective to achieve the benefit claimed to be essential.

39. One comment from a dermatologist requested that cortisone sprays for topical use be exempt from the ban on chlorofluorocarbons for propellant uses. The comment stated that in an aerosol form, the product has the unique property of being able to penetrate scalp lesions in such a way as to clear them. The comment also stated that these products are used in a most sparing manner and that the tiny amount of chlorofluorocarbon escaping into the atmosphere by this prescription drug could not possibly alter the ozone layer of the atmosphere.

Although the aerosol product may have certain advantages over other dosage forms, the comment did not indicate why another dosage form, such as a lotion, could not be used. Further, the comment did not indicate why a propellant other than a chlorofluorocarbon could not be used in such a topical product. Therefore, the comment is not accepted.

40. One comment requested that proposed § 2.125(i) be modified to allow for clinical testing of chlorofluorocarbon-containing products after December 15, 1978, if the testing is performed to establish the essentiality of these drug products and, thus, is needed to support any petition submitted after that date. It was argued that as the proposal was worded, any testing to prove that an investigational new drug (IND) drug product containing a chlorofluorocarbon propellant is safe, effective, or essential, must be completed by December 15, 1978. The comment also suggested that proposed § 2.125(i) be modified to allow FDA to grant conditional approval of essentiality for an IND drug, provided the sponsor submits adequate preclinical animal or human clinical data to support a petition. This approval would be conditional upon the sponsor's proof, submitted at a later date, that the chlorofluorocarbon-containing drug product is safe and effective.

As proposed, § 2.125(i) would require a sponsor of an IND for a drug product containing a chlorofluorocarbon propellant either to reformulate the product or submit a petition to show that the use of the chlorofluorocarbon is an essential use. The Commissioner recognizes that there may be instances where the use of a chlorofluorocarbon propellant in an IND drug product is not just for convenience but may prove to be an essential use, provided sufficient time is permitted to perform the necessary testing. The Commissioner, therefore, agrees with the comment that § 2.125(i) should be revised to permit such studies to continue after December 15, 1978, and to allow new studies to begin, if the use of the chlorofluorocarbon in the drug product has a reasonable likelihood of being considered an essential use. The revision to § 2.125(i) however, must not permit a study to continue or to begin if any of the following circumstances exist: (1) The chlorofluorocarbon is used only for convenience; (2) the product could be administered by another dosage for; or (3) the use of the chlorofluorocarbon represents a use that is identical or similar to a use that has previously been determined to be a nonessential use of chlorofluorocarbon. To permit the continuation of use of a chlorofluorocarbon in an IND drug product in only appropriate instances, § 2.125(i) has been revised to provide that the sponsor of an IND or INAD for a drug product containing a chlorofluorocarbon shall either amend the IND or INAD before December 15, 1978, to remove the chlorofluorocarbon, submit a petition showing that the use of chlorofluorocarbon is essential, or submit a petition requesting permission to perform studies while collecting the data to show that the use of the chlorofluorocarbon is essential. In this latter case, the petition must describe the drug product, indicate why a chlorofluorocarbon-propelled product is being investigated rather than another dosage form, and explain the benefit of such a product.

41. One comment urged that December 1980 be the effective date to discontinue manufacturing products containing a chlorofluorocarbon, and April 15, 1978, be the effective date for the prohibition on introducing products containing a chlorofluorocarbon in interstate commerce. It was argued that this delay would not cause any significant harm to the environment and would allow industry a more reasonable time to develop alternative propellants. Another comment cited advantages of two topical aerosol products that were not declared to be essential, and requested that the proposed October 1, 1978, deadline for the submission of supplemental NDA's be extended 1 year. This additional time is needed to develop a satisfactory reformulation, provide appropriate stability data and perform sufficient testing as to the appropriateness of an alternative delivery system. This comment also requested that the other proposed dates be delayed by 1 year.

In comment 11 of this document and in comment 14 of the preamble to the proposed phaseout regulations (see the FEDERAL REGISTER of May 13, 1977 (42 FR 24539)), the Commissioner discussed the proposed effective dates and concluded that a delay to test the safety of a possible new propellant was not warranted. Likewise, he concluded that the proposed regulation provided companies a reasonable time to reformulate their products and perform the necessary testing. The Commissioner has reexamined those conclusions and reaffirms his previous position that the proposed effective dates provide a reasonable time for manufacturers. Therefore, these comments are not accepted.

42. One comment suggested that the time for obtaining final approval of an NDA for a product containing a chlorofluorocarbon for an essential use should be 2½ years after publication of the final regulation. The comment

indicated that in the past FDA has demonstrated difficulty in acting swiftly on submitted routine NDA's.

The majority of products containing a chlorofluorocarbon for an essential use are already covered by NDA's. Therefore, the agency believes it can handle expeditiously the NDA's for the few remaining products determined to contain a chlorofluorocarbon for an essential use. Further, although these NDA's must be submitted by June 15, 1978, a manufacturer may submit its NDA sooner, and, if it does so, the agency would have more than 6 months to review the application. In addition, as the comment stated, the safety and efficacy of the products listed in § 2.125(e) are not in question, which should help in the prompt review of these applications. For these reasons, the comment is not accepted.

43. The citizen petition from the Michigan Department of Public Health referred to in comment 28 also requested that the Commissioner ban drugs containing chlorofluorocarbon compounds.

The petition supports the action being taken in this order.

C. *Medical devices and diagnostic products.* 44. Two comments requested exemption from the phaseout regulation for a silicone fluid dispensed with a chlorofluorocarbon propellant to be used for the protection and lubrication of surgical instruments. It was stated that no other propellant on the market could meet the manufacturer's requirements.

The Commissioner agrees that other suitable propellants may be unavailable at the present time. However, the Commissioner does not accept the position that lubricants and protective coatings of silicone applied by spray are an essential use of chlorofluorocarbons since lubricants and protective coatings may be applied by nonspray techniques.

45. An exemption was requested for a hand lotion to protect against skin irritation and chapping for use by dentists. This product uses chlorofluorocarbons both as a propellant and as a solvent for the active ingredient, and the use of chlorofluorocarbons was felt to be essential as the only satisfactory nontoxic solvent.

The Commissioner does not agree that such a hand-protective substance using chlorofluorocarbons possesses sufficiently unique properties as to constitute an essential use of chlorofluorocarbons. As the submission itself noted, protective hand lotions are available in other forms, such as creams. For these reasons and those noted in comment 38 of this document relating to dual functions of chlorofluorocarbons, the request is denied.

46. A comment was received requesting essential use status for a chlorofluorocarbon-containing aerosol for use in checking dental occlusion, contending that no suitable replacement for the chlorofluorocarbon propellant was available.

The Commissioner does not agree that such use of chlorofluorocarbons for propelling diagnostic material for checking dental occlusion is an essential use of chlorofluorocarbons since nonspray techniques for checking dental occlusion are available.

47. One comment was received urging the Commissioner to determine that cytology fixative spray is an essential use of chlorofluorocarbons and that the health benefits of such use outweigh the ozone depletion risks.

The Commissioner does not agree that the use of chlorofluorocarbons is essential in this application. The use of chlorofluorocarbons to propel cytological fixatives had previously been considered essential and exempted from the warning label requirement (see the FEDERAL REGISTER of April 29, 1977 (42 FR 22034)) and the proposal to prohibit nonessential propellant uses of chlorofluorocarbons (see the FEDERAL REGISTER of May 13, 1977 (42 FR 24541)). Since that time, the agency reexamined the matter and finds that the effectiveness of the cytological fixative is not dependent upon chlorofluorocarbon propellants. The fixative may be applied satisfactorily by means of a spray pump bottle or a dropper, thereby obviating the need for chlorofluorocarbon propellants. In addition, for those specimens retained within a laboratory, a 95 percent alcohol fixative is a satisfactory preparation. To provide additional information to show that the use of chlorofluorocarbons in the application of fixatives to cytological preparations is essential, a citizen's petition as provided for in 21 CFR 10.30 may be filed. The Commissioner will take action on such a submission in an expeditious manner.

VII. ALTERNATIVES

48. Several comments addressed technical feasibility and health considerations of alternative delivery systems. Two companies submitted descriptions of recently invented non-gas-propelled aerosol delivery systems. Industry associations submit that: (a) Hydrochlorofluorocarbons have the greatest technical feasibility to replace chlorofluorocarbon propellant uses, but further toxicological testing is necessary to determine their safety (at least for hydrochlorofluorocarbons 22 and 142B*); (b) hydrocarbons present a flammability hazard and may have inferior spray characteristics; (c) compressed gases have inferior spray characteristics; and (d) nonaerosol alternatives may not be acceptable to many consumers and production of these units might fall short of the demand under the proposed phaseout timetable. In contrast: (a) Several consumers commented on the ease with which they have been able to switch to nonchlorofluorocarbon-propelled products; (b) intensive advertising programs have been initiated by the deodorant, antiperspirant, and hair care industries (ustin about 90 percent of the 1974 total amount of chlorofluorocarbons in FDA-regulated aerosol products (Ref. 16)) to promote hydrocarbon-propelled and nonaerosol replacement products, showing that alternatives to chlorofluorocarbon propellants in at least these products are already being marketed, and (c) no shortages of nonaerosol products at the retail level have been reported despite industry's reported 40 percent drop in the sale of chlorofluorocarbons used as propellants. Additionally, as noted in one comment, aerosolized products require 2 to 10 times as much energy to produce as nonaerosol alternatives (Ref. 17).

The Commissioner agrees with these latter comments. In addition he has already responded to comments relating to the safety of alternative product delivery systems in the following manner (see the FEDERAL REGISTER of April 29, 1977 (42 FR 22027)):

The Commissioner recognizes that it is possible that alternative products may also pose hazards of various types. The present action relates only to the adverse effects of chlorofluorocarbons upon stratospheric ozone, and the potential physiologic hazards from other products are not within the scope of this regulation. It is the Commissioner's position that manufacturers should substantiate the safety of all their products before marketing, and under 21 CFR 740.10, cosmetic manufacturers are required to warn consumers if they have failed to perform testing to substantiate the safety of products. Furthermore, products must bear warnings necessary or appropriate to prevent a health hazard that may be associated with the product (21 CFR 740.1). If the adverse reactions associated with a product are unreasonable, in number or severity, FDA will take regulatory action. Citizens may petition FDA to take regulatory action with respect to any risk posed by regulated products. It would not be appropriate, however, to leave an unsafe product on the market, because the possible risks of alternatives were not yet fully known and might also be unacceptable. Instead, no unsafe products should be marketed. The Food and Drug Administration endeavors to ensure the safety of all cosmetics and products it regulates; FDA resources are limited, however, and in some instances, including with respect to cosmetics, FDA's statutory authority needs strengthening. Within these constraints, FDA will continue to act to ensure the safety of all the products subject to the FFDCA.

The Commissioner notes that hydrocarbon propellants are being formulated with methylene chloride in part to reduce the flammability of these propellants. Methylene chloride is a mu-

*Hydrochlorofluorocarbons 22 and 142B: $CHClF_2$ and $CClF_2—CH_3$, respectively.

taken in bacteria (Ref. 18). Additionally, methylene chloride has been shown to induce transformations in rat embryo cells grown in vitro (Ref. 19). Methylene chloride is currently being tested for carcinogenicity by Dow Chemical and the National Cancer Institute. FDA will review the results of these tests when they become available and take appropriate action.

FINAL ENVIRONMENTAL IMPACT STATEMENT

The Food and Drug Administration has determined that this action will likely cause significant environmental impacts. Therefore, the agency prepared a draft environmental impact statement (DEIS) on the proposed action. Comments on the DEIS have been considered and a final EIS prepared. The final EIS is available for public inspection between 9 a.m. and 4 p.m., Monday through Friday, in the office of the Hearing Clerk (HFC-20), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. A limited number of copies will be available upon request from the Hearing Clerk.

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2. National Academy of Sciences, Committee on Impacts of Stratospheric Change, Panel on Atmospheric Chemistry, "Halocarbons: Effects on Stratospheric Ozone," 1976.

3. National Aeronautics and Space Administration, Goddard Space Flight Center, Reference Publication 1010: "Chlorofluoromethanes and the Stratosphere," 1977.

4. National Aeronautics and Space Administration, Assessment Report: "Effects of Chlorofluoromethanes on Stratospheric Ozone," 1977.

5. Food and Drug Administration, Final Environmental Impact Statement, "Fluorocarbons: Environmental and Health Implications," 1977.

6. Food and Drug Administration, Economic Impact Statement of Proposed Rule Making: "Certain Fluorocarbons (Chlorofluorocarbons) in Food, Food Additive, Drug, Animal Food, Animal Drug, Cosmetic and Medical Device Products as Prohibition on Use," 1977.

7. United Nations Environment Programme, "Meeting of Experts Designated by Governments, Intergovernmental and Non-Governmental Organizations on the Ozone Layer," Washington, D.C., March 1-9, 1977.

8. Environmental Protection Agency, Food and Drug Administration, and Consumer Product Safety Commission, "International Meeting on Regulation of Chlorofluorocarbons," Washington, D.C., April 26-28, 1977.

9. National Academy of Sciences, Committee on the Impact of Stratospheric Change, "Response to the Ozone Protection Sections of the Clean Air Act Amendments of 1977: An Interim Report," 1977.

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11. Ridley, B. A., J. T. Bruin, H. I. Schiff, and J. C. McConnell, "Altitude Profile and Sunset Decay Measurements of Stratospheric Nitric Oxide," Atmosphere, 14(3):180-188.

12. Hill, W. J. and P. N. Sheldon, "Statistical Modeling of Total Ozone Measurements with an Example Using Data from Arosa, Switzerland," Geophysical Research Letters, 2(12):541-544, 1975.

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15. International Research and Technology Corporation, "The Economic Impact of Potential Regulation of chlorofluorocarbon-Propelled Aerosols," Prepared for Environmental Protection Agency, Food and Drug Administration, and Consumer Product Safety Commission under EPA Contract No. 68-01-1918, 1977.

16. Klauder, D. S., "Fluorocarbons in Aerosol Products Subject to the Jurisdiction of the Food and Drug Administration," (unpublished staff memorandum), 1976.

17. Center for Science in the Public Interest, "Aerosol Sprays," 1976, p. 21.

18. Simmon, U. F., K. Kauhanen, and R. G. Tardiff, "Mutagenic Activity of Chemicals Identified in Drinking Water," In "Progress in Genetic Toxicology," Edited by D. Scott, B. A. Bridges, F. H. Sobels, Elsevier-North Holland Publishing Co., New York (in press).

19. Price, P. J., E. M. Hassett, and J. I. Mansfield, "Transforming Activities of Trichloroethylene and Proposed Industrial Alternatives," (to be published in the March issue of In Vitro), 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 301, 402, 409, 501, 502, 505, 507, 512, 601, 701(a), 52 Stat. 1042-1043 as amended, 1046-1047 as amended, 1049-1054 as amended, 1055, 57 Stat. 463 as amended, 72 Stat. 1735-1788 as amended, 82 Stat. 343-351 (21 U.S.C. 331, 342, 348, 351, 352, 355, 357, 360b, 361, 371(a))) and the National Environmental Policy Act of 1969 (sec. 102(2), 83 Stat. 853 (42 U.S.C. 4332)) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

SUBCHAPTER A—GENERAL

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

1. By adding new Subpart G consisting at this time of § 2.125 to read as follows:

Subpart G—Provisions Applicable to Specific Products Subject to the Federal Food, Drug, and Cosmetic Act

§ 2.125 Use of chlorofluorocarbon propellants in self-pressurized containers.

(a) As used in this section:

(1) "Chlorofluorocarbon" means any fully halogenated chlorofluoroalkane.

(2) "Propellant" means a liquefied or compressed gas that is used in whole or in part to expel from the same self-pressurized container or from a separate container a liquid or solid material different from the propellant, but the term does not include the use of a chlorofluorocarbon as an aerating agent for foamed or sprayed food products.

(b) Chlorofluorocarbons are widely used in products subject to the Federal Food, Drug, and Cosmetic Act, with the principal use being as propellants in self-pressurized containers. Information recently developed indicates that chlorofluorocarbons may reduce the amount of ozone in the stratosphere and thus increase the amount of ultraviolet radiation reaching the earth. An increase in ultraviolet radiation may increase the incidence of skin cancer, change the climate, and produce other effects of unknown magnitude on humans, animals, and plants. Chlorofluorocarbons may also affect the climate by increasing infrared absorption in the atmosphere.

(c) Except as provided in paragraph (e) of this section, any food, drug, device, or cosmetic in a self-pressurized container that contains a chlorofluorocarbon propellant is adulterated and/or misbranded in violation of the act, and any drug product in a self-pressurized container that contains a chlorofluorocarbon propellant is a new drug or a new animal drug.

(d) The use of a chlorofluorocarbon as a propellant in a self-pressurized container of a drug product will not result in the drug product being adulterated and/or misbranded provided a new drug application or new animal drug application for the drug product has been approved, a petition has been filed as provided by paragraph (f) of this section and paragraph (e) of this section has been amended to specify the use as essential.

(e) The adulteration and misbranding provisions of paragraph (c) of this section shall not apply to the following essential uses of chlorofluorocarbons:

(1) Metered-dose steroid human drugs for nasal inhalation,

(2) Metered-dose steroid human drugs for oral inhalation,

(3) Metered-dose adrenergic bronchodilator human drugs for oral inhalation,

(4) Contraceptive vaginal foams for human use, and

(5) Metered-dose ergotamine tartrate drug products administered by oral inhalation for for use in humans.

(f) Any person may file a petition in accordance with Part 10 of this chapter to amend paragraph (e) of this section to specify a use of chlorofluorocarbons in a product as not being subject to the adulteration and misbranding provisions in paragraph (c) of this section. The petition must be supported by an adequate showing that:

(1) There are no technically feasible alternatives to the use of a chlorofluorocarbon in the product.

(2) The product provides a substantial health benefit, environmental benefit, or other public benefit that would not be obtainable without the use of the chlorofluorocarbon, and

(3) The use does not involve a significant release of chlorofluorocarbons into the atmosphere or that the release is warranted in view of the consequence if the use were not permitted.

(g) Any holder of an approved new drug application or new animal drug application for a drug product containing a chlorofluorocarbon in a self-pressurized container, except those drug products listed in paragraph (e) of this section, shall submit to the Food and Drug Administration on or before October 1, 1978, either a supplemental application providing for a revised formulation complying with the requirements of § 314.8 or § 514.8 of this chapter or a letter requesting that a new drug application or a new animal drug application for the drug product containing chlorofluorocarbon be withdrawn and that the right to a hearing on the withdrawal of the application is waived.

(h) The manufacturer of any drug product listed in paragraph (e) of this section that is not covered by an approved new drug application or new animal drug application shall submit a new drug application in accord with § 314.1(f) or § 514.1 of this chapter on or before June 15, 1978. The abbreviated new drug application submitted in accord with § 314.1(f) of this chapter shall contain full information with respect to items 6 (components), 7 (composition), 8 (methods, facilities, and controls), and 9 (samples) of new drug application form FD-356H.

(i) Any sponsor of a "Notice of Claimed Investigational New Drug" (IND) or "Notice of Claimed Exemption for a New Animal Drug" (INAD) for a drug product containing a chlorofluorocarbon shall:

(1) Amend the IND or INAD on or before December 15, 1978, to revise the formulation removing the chlorofluorocarbon.

(2) Submit the information required under paragraph (f) of this section to amend paragraph (e) of this section to show that the use of chlorofluorocarbon is essential, or

(3) Submit the information required under paragraph (j) of this section requesting that studies with the drug product containing a chlorofluorocarbon propellant be allowed to be performed.

(j) Any sponsor of an IND or INAD who wishes to initiate or continue a study beyond December 15, 1978; on a drug product containing a chlorofluorocarbon shall submit a petition in accordance with part 10 of this chapter requesting that studies be permitted to collect the data to show that the use of the chlorofluorocarbon is an essential use. The petitions must be supported by the following:

(1) A description of the drug product,

(2) An explanation why a chlorofluorocarbon propellant is used in the product rather than another propellant or another dosage form of the product, and

(3) The benefit that the investigational product is believed to have and that the sponsor hopes to demonstrate by the studies.

(k) The Commissioner will initiate action to withdraw approval of an application or terminate an IND or INAD notice in accordance with the applicable provisions of section 505 of the act and parts 312 and 314 of this chapter, or section 512 of the act and parts 511 and 514 of this chapter upon failure of a holder of an approved new drug application or approved new animal drug application or sponsor of an IND or INAD notice to comply with the applicable provisions of this section.

(l) Food, drug, device, or cosmetic products manufactured or packaged on or after December 15, 1978, and finished products initially introduced into interstate commerce on or after April 15, 1979, shall comply with this regulation.

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

PART 172—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

Subpart D—Specific Usage Additives

2. By amending § 173.345 by revising paragraphs (b) and (c)(1)(i) to read as follows:

§ 173.345 Chloropentafluoroethane.

* * * * *

(b) The additive is used or intended for use alone or with one or more of the following substances: Carbon dioxide, nitrous oxide, propane, and octafluorocyclobutane complying with § 173.360 as an aerating agent for foamed or sprayed food products, with any propellant effect being incidental and no more than is minimally necessary to achieve the aerating function, except that use is not permitted for those standardized foods that do not provide for such use.

(c) * * *

(1) * * *

(i) The name of the additive, chloropentafluroethane.

* * * * *

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

Subpart C—Substances Prohibited From Direct Addition to Human Food Through Food-Contact Surfaces

3. By adding new § 189.191 to read as follows:

§ 189.191 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in human food as propellants in self-pressurized containers is prohibited as provided by § 2.125 of this chapter.

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 300—GENERAL

4. By adding new Subpart C consisting at this time of § 300.100 to read as follows:

Subpart C—Substances Generally Prohibited From Drugs

§ 300.100 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in human drugs as propellants in self-pressurized containers is generally prohibited except as provided by § 2.125 of this chapter.

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 500—GENERAL

Subpart B—Specific Administrative Rulings and Decisions

5. By adding new § 500.49 to read as follows:

§ 500.49 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons as propellants in self-pressurized containers is prohibited from use in all animal drugs, animal food, and related products as provided by § 2.125 of this chapter.

SUBCHAPTER G—COSMETICS

PART 700—GENERAL

Subpart B—Requirements for Specific Cosmetic Products

6. By adding new § 700.23 to read as follows:

§ 700.23 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in cosmetics as propellants in self-pressurized containers is prohibited as provided in § 2.125 of this chapter.

SUBCHAPTER H—MEDICAL DEVICES

PART 801—LABELING

Subpart H—Special Requirements for Specific Devices

7. By adding new § 801.417 to read as follows:

§ 801.417 Chlorofluorocarbon propellants.

The use of chlorofluorocarbon in devices as propellants in self-pressurized containers is generally prohibited except as provided in § 2.125 of this chapter.

Effective dates. These regulations shall be effective on December 15, 1978, for the manufacturing or packaging of products subject to this regulation, and April 15, 1979, for the initial introduction into interstate commerce of products subject to this regulation.

(Secs. 301, 402, 409, 501, 502, 505, 507, 512, 601, 701(a), 52 Stat. 1042-1043 as amended, 1046-1047 as amended, 1049-1054 as amended, 1055, 57 Stat. 463 as amended, 72 Stat. 1785-1788 as amended, 32 Stat. 343-351 (21 U.S.C. 331, 342, 348, 351, 352, 355, 357, 360b, 361, 371(a)); sec. 102(2), 83 Stat. 853 (42 U.S.C. 4332).)

Dated: February 3, 1978.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc. 78-6039 Filed 3-9-78; 8:45 am]

[6560-01]

Title 40—Protection of Environment

[FRL-885-6]

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER R—TOXIC SUBSTANCES CONTROL ACT

PARTS 712, 762—FULLY HALOGENATED CHLOROFLUOROALKANES

AGENCY: Environmental Protection Agency.

ACTION: Final rules.

SUMMARY: On May 13, 1977, the Environmental Protection Agency (EPA) proposed a rule (42 FR 24542) which would prohibit almost all of the manufacture, processing, and distribution in commerce of fully halogenated chlorofluoroalkanes (hereinafter referred to as chlorofluorocarbons) for those aerosol propellant uses which are subject to the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq. This rule and a related rule on reporting are now being promulgated in final form and will become effective October 15, 1978.

In a related action, the Food and Drug Administration (FDA) is publishing a final rule in today's FEDERAL REGISTER to ban the use of chlorofluorocarbon aerosol propellants in most food, drug, and cosmetic products.

The intent of these rules is to reduce emissions of chlorofluorocarbons to the atmosphere, thereby reducing the health and environmental risk caused by depletion of the ozone layer.

The promulgation of these rules concludes the first phase of EPA's investigation of chlorofluorocarbon emissions. A second phase investigation involving the nonaerosol propellant uses (e.g., refrigeration, foam blowing, and solvent) is ongoing.

EFFECTIVE DATES: October 15, 1978: Prohibition of Manufacturing. December 15, 1978: Prohibition of Processing and Distribution in Commerce.

INFORMATION CONTACT:

Perry Brunner, Office of Toxic Substances (TS-788), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 202-426-9000.

Joni T. Repasch is the Record and Hearing Clerk for this rulemaking. The official record of rulemaking is located in Room 529 WSME, EPA Headquarters, 401 M Street SW., Washington, D.C. 20460, 202-755-1138. The record is available for viewing and copying from 9 a.m. to 4 p.m., Monday through Friday, excluding holidays.

SUPPLEMENTARY INFORMATION: Under TSCA § 6 and its implementing regulations, 42 CFR 750, EPA is required to publish a statement discussing the factual, legal, analytical, and policy considerations which led to issuance of the rule, including the factors listed in TSCA § 6(c)(1). This preamble, the preamble to the proposed rule, the "Final Support Document," and the "Essential Use Determinations—Revised" are intended to fulfill that requirement.

Other major documents in the record are "Chlorofluorocarbon Problem Assessment" and "Economic Impact of Potential Regulation of Fluorocarbon Aerosols".

A list of all material in the record is found at the end of this preamble. Copies of the major documents may be obtained from Mrs. Joni Repasch at the address stated above.

I. EFFECTS OF CHLOROFLUOROCARBONS ON HEALTH AND THE ENVIRONMENT

Chlorofluorocarbons produce a risk to human health and the environment by causing depletion of the ozone layer. Upon release from an aerosol product or other source, the compounds diffuse slowly to the stratosphere. When they reach the stratosphere, they undergo photochemical decomposition which liberates free chlorine radicals. The chlorine radicals enter into a catalytic chain reaction with ozone molecules, and the net result is a depletion of the ozone layer.

The ozone layer helps shield the Earth's surface from ultraviolet (UV) radiation. As the layer is depleted, the Earth's surface is bombarded with more UV radiation. Current estimates are that if chlorofluorocarbon emissions continue at the 1975 rate, the ozone layer would be depleted ultimately by 11 to 16 percent.

While the effects of ozone depletion are very difficult to quantify, they are quite serious. The major immediate concern is that increased UV radiation leads to a statistically significant increase in skin cancer. Some negative effects on plants and animals are likely. There are also predictions of adverse effects because of an increase in the Earth's temperature ("greenhouse effect") and changes in climate. The health and environmental consequences of these and other changes are not well understood. However, there is considerable concern that these consequences will produce significant adverse effects.

II. USES, BENEFITS, AND ALTERNATIVES

In 1975, approximately one-half of the chlorofluorocarbons produced in the United States were used as aerosol propellants. Since then this figure has dropped considerably. Of the nonaerosol production, approximately one-half is used as refrigerants, and most of the remainder is used as solvents and foam blowing agents.

Chlorofluorocarbons are frequently the preferred propellant in aerosol products because of their nonflammability, their excellent dissolving (solvent) ability, and their fine spray characteristics. However, hydrocarbon and carbon dioxide propellants are available as alternatives to chlorofluorocarbons for many aerosol products. In addition, there are nonaerosol

alternatives such as pump sprays, waxes, liquids, and powders for most aerosol uses. In those cases where there is no alternative to a chlorofluorocarbon spray and the use appears essential, the Administrator has provided for exemptions from this regulation.

III. Economic Considerations

Over the past few years, use of chlorofluorocarbon aerosol propellants has decreased substantially. Five years ago, chlorofluorocarbons were used in 50 percent of aerosol products; it is estimated that they are now used in 20 percent. Because of the reduction in use, the economic impact of implementing EPA's rules will be much smaller than it would have been had they become effective sooner. The economic effects will be felt by three major groups in the chlorofluorocarbon industry: manufacturers, processors (fillers), and distributors (marketers). The combined impact of the EPA and FDA rules is expected to affect significantly the manufacturers and the fillers. EPA believes that the distributors are capable of switching to other products without significant costs.

Decreased sales of chlorofluorocarbon propellants have a direct impact both on the manufacturers of chlorofluorocarbons and the manufacturers of their chemical precursors. However, most of these manufacturers are large corporations which should be able to make the financial adjustment.

Fillers, on the other hand, will be significantly affected, and some probably will be severely affected. However, singling out small fillers for special treatment would undercut the effect of this regulation, lead to other economic dislocations, and hamper the Agency's enforcement efforts.

Consumers of household products stand to gain financially. Products containing chlorofluorocarbon propellants are more expensive per application than are products containing alternative propellants and nonaerosol products. Industrial consumers may have to make adjustments in products or processes. However, the essential use exemptions should alleviate any major adverse impact on industrial production outside the chlorofluorocarbon industry. Adverse effects on technological innovation are not expected.

IV. Finding of Unreasonable Risk

The Administrator finds that the continued depletion of stratospheric ozone as the result of discharges from nonessential aerosol products containing fully halogenated chlorofluoroalkane propellants presents an unreasonable risk of injury to health and the environment. Since this finding was proposed (42 FR 24545, May 13, 1977), the Administrator has reviewed the numerous comments received and the new scientific data which has become available. The Administrator remains convinced that promulgation of this rule at this time is necessary in order to reduce the risk of injury from chlorofluorocarbon aerosol propellant emissions to an acceptable level. A full explanation of his reasons and response to comments appears in the "Final Support Document."

Because chlorofluorocarbon emissions anywhere in the world deplete the ozone layer and adversely affect health and the environment of the United States, the Administrator finds that chlorofluorocarbon discharges from aerosol propellant articles made in the United States and shipped abroad also cause an unreasonable risk of injury.

V. Least Burdensome Approach

EPA has taken steps to reduce the burden of this regulation. Foremost was the decision to postpone a finding of unreasonable risk associated with nonpropellant uses until they are investigated more fully. Secondly, exemptions have been given for certain essential uses including nonconsumer electronics/electrical and aviation uses. In addition, by making the manufacturing ban effective 18 months from the proposal date instead of making it effective sooner, the Administrator has significantly reduced the economic impact.

EPA rejects the idea of requiring warning labels on chlorofluorocarbon products as an alternative to this rule. EPA believes that a labeling requirement would be insufficient to reduce the unreasonable risk from chlorofluorocarbon aerosol emissions. In addition, the Agency believes that the continued use of chlorofluorocarbons by some consumers will result in the involuntary exposure of the entire public to hazards created by the user population.

VI. Relationship of TSCA to Other EPA Authorities

EPA previously proposed a finding under §9(b) of TSCA that it was in the public interest to use TSCA instead of the Clean Air Act or the Federal Insecticide, Fungicide, and Rodenticide Act to regulate aerosol propellant uses of chlorofluorocarbons (42 FR 24545). EPA believes that that discussion of the disadvantages of using those acts remains applicable, and the Agency hereby adopts its proposed §9(b) findings.

The Clean Air Act Amendments of 1977 do not affect the Agency's authority to use TSCA to regulate the aerosol uses of chlorofluorocarbons. (42 U.S.C. 7458). The Amendments specifically permit EPA to promulgate rules proposed under TSCA prior to enactment of the Amendments, and the legislative history contemplates that EPA would do so.

VII. Phase II

The Administrator recognizes that this rule and the corresponding FDA regulation may not be adequate to fully protect the ozone layer. As EPA has indicated previously, nonpropellant uses such as refrigerants and solvents are being examined in the second phase investigation. A second public meeting on Phase II uses to gather pertinent information was held by EPA, FDA, and the Consumer Product Safety Commission (CPSC) in February.

In addition to EPA's general authority under TSCA to regulate chemical substances, the 1977 Amendments to the Clean Air Act specifically address the protection of the ozone layer (42 U.S.C. 7450). These provisions require EPA and other Federal agencies to conduct research and to submit reports to Congress on the stratosphere. By August 1979, EPA must submit a report to Congress that recommends further regulatory steps that may be needed. At that time the Administrator must propose regulations "for the control of any substance, practice, process, or activity (or any combination thereof) which in his judgment may be reasonably anticipated to affect the stratosphere, especially ozone in the stratosphere, if such effect in the stratosphere may reasonably be anticipated to endanger public health or welfare." (42 U.S.C. 7457).

EPA, CPSC, and FDA consequently will be engaged in an ongoing review of the ozone problem after this regulation has been promulgated and becomes effective. Should it become apparent in the future that chlorofluorocarbons do not pose an unreasonable risk, the Agency will take appropriate action to rescind or modify this rule.

VIII. Essential Uses

During the development of this rule, a number of persons requested exemptions for the use of certain products which contain chlorofluorocarbon propellants. Essential uses that were granted exemptions are listed in §762.21 of the rule. The criteria used, the products considered, and the information analyzed in evaluating all requests are found in the support document "Essential Use Determinations-Revised." All of the essential uses will be reevaluated during the second phase of EPA's regulation of chlorofluorocarbons.

The four most significant categories of essential uses considered by EPA were pesticides, products used by the Department of Defense (DOD), uses in the electronics/electrical industries, and uses in the aviation industry. For the reasons described in the essential

use document, only a few pesticide uses were granted exemptions. DOD uses are covered by a Memorandum of Understanding between EPA and DOD which is publicly available. Under its terms DOD will be able to use only those products necessary to maintain the military preparedness of the United States. DOD will switch to alternative products where they exist.

Electronic/electrical uses and aviation uses are broad categories of uses. These categories were given exemptions because most of the products within both of the categories are important for preserving public safety and promoting public welfare. At this time, the Agency does not have the information necessary for limiting these broad exemptions in order to identify nonessential products. However, the Agency will examine these products in depth during its Phase II examination of chlorofluorocarbons.

IX. Preemption of State Laws

This regulation affects the authority of a State to establish regulations concerning chlorofluorocarbons. Section 18 of TSCA provides that when EPA restricts the manufacture of or otherwise regulates a chemical under section 6, a State may only issue requirements which are identical, which are mandated by other Federal laws, or which prohibit the use of the chemical. Thus, this regulation preempts any less restrictive State regulation addressed to the same risk.

X. Legal Considerations

These rules are being promulgated under the authority of sections 6, 8, and 12 of TSCA (15 U.S.C. 2605, 2607, 2611).

A. Relationship of Rule to Federal Food, Drug, and Cosmetic Act

Section 762.11, as proposed, prohibited any person from manufacturing chlorofluorocarbons for any aerosol propellant use after October 15, 1978, except for those uses found to be essential by EPA and FDA. Several commenters challenged EPA's legal authority to do this under TSCA section 3(2)(B)(vi). They specifically argued that TSCA does not empower EPA to regulate all the manufacture of a chemical that has many uses if that chemical sometimes functions as a food, drug, or cosmetic.

EPA concurs in large part with these comments and has amended the regulation accordingly. Section 762.11(a)(1) no longer prohibits manufacture under TSCA for food, food additive, drug, cosmetic, or device uses (hereinafter referred to as "FFDCA substances"). However, a rule promulgated by the FDA today prohibits most uses of chlorofluorocarbons in FFDCA substances.

EPA agrees that TSCA does not provide the authority to regulate FFDCA substances insofar as a chemical is actually manufactured, processed, or distributed in commerce for use as an FFDCA substance. The Agency also recognizes that the definition of "drug" includes a chemical intended for use as a component of a drug and that components of foods, food additives, cosmetics, and devices are similarly treated in the FFDCA. Chlorofluorocarbons can, however, be used either as components of FFDCA substances or for other purposes. Because all chlorofluorocarbon propellants are manufactured in the same way, physical examination of a chlorofluorocarbon does not reveal its intended use. The manufacturer's intent determines the prospective use.

In order to be exempt from this section 6 rule, the manufacturer would have the burden of demonstrating his intent to manufacture the propellant for use as an FFDCA substance. EPA has concluded that where a chemical such as a chlorofluorocarbon is being manufactured both for use as an FFDCA substance and for other uses, the chemical will be presumed to be a chemical substance under TSCA unless it clearly can be shown that the chemical actually is being manufactured for use as an FFDCA substance. This presumption is particularly appropriate here since it is anticipated that the vast majority of chlorofluorocarbons manufactured after October 15, 1978, will be produced for uses other than uses as FFDCA substances, i.e., for propellant uses found to be essential under EPA's regulation or for nonpropellant uses such as refrigerants and solvents.

As a practical matter, EPA and FDA believe that the legal determination of whether a chlorofluorocarbon is a TSCA chemical substance or an FFDCA substance will be of minimal significance except with respect to separate enforcement of EPA's and FDA's regulations. Both rules have the same general purpose, namely, to ban most uses of chlorofluorocarbons as aerosol propellants. There is no regulatory gap. If a chlorofluorocarbon is not a TSCA chemical substance, it is an FFDCA substance, and vice versa.

B. Relationship of Rule to Federal Insecticide, Fungicide, and Rodenticide Act

Proposed § 762.12 did not prohibit processing of chlorofluorocarbon propellants for use in pesticide products. EPA requested comments on whether TSCA section 3(2)(B)(ii) permits EPA to regulate under TSCA the processing of chlorofluorocarbons which may take place as part of the manufacture of pesticide products (42 FR 24545). No comments on this point were received. Having considered the issue further, both in connection with this regulation and the TSCA section 8(a) inventory reporting regulation, EPA has concluded that there is sufficient authority under TSCA to ban the processing of chlorofluorocarbons for use in pesticides (i.e., incorporation of chlorofluorocarbons into aerosol pesticides).

In order to be considered a pesticide, a chemical substance must be intended for use as a pesticide.[1] Raw materials, intermediates, and inert ingredients such as chlorofluorocarbons used in the manufacture of a pesticide are not regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) unless they happen to be pesticides themselves. A chlorofluorocarbon would fall within the jurisdiction of FIFRA only when it has become a component of a pesticide product. This would not occur until it was actually mixed with or combined with the active ingredient (the pesticide).

The legislative history of TSCA indicates that a particular chemical could be subject to both TSCA and FIFRA at different points in time. When the bill which became TSCA was under Senate floor consideration, Senator Allen specifically addressed the interface between FIFRA and TSCA noting that the bill's provision meant that: "* * * any chemical or toxic substance would first be subject to the provisions of TSCA and yet when it becomes a component of a pesticide, it would be subject to FIFRA. In many instances, the manufacturer of the component is also the manufacturer and registrant of the pesticide." Committee on Interstate and Foreign Commerce, 94th Cong., 2d Sess. Legislative History of the Toxic Substances Control Act 332 (1976).

The change in § 762.12 does not significantly alter the practical impact of this regulation because a ban on manufacturing for pesticide uses was previously proposed (§ 762.11). It will, however, greatly aid the Agency in its enforcement efforts since the enforcement emphasis will be on processors.

C. Exports

Several commenters argued that the proposed ban on export is beyond EPA's authority under TSCA. It was stated that the export of food, drugs, and cosmetics is being regulated contrary to the intent of section 3(2) of TSCA and section 801(d) of the FFDCA. The Administrator disagrees in part with the above analysis; however, changes in the rule make it unnecessary to resolve those issues.

The only regulation of exports in the final rule appears in the processing ban provision (§ 762.12(b)). Pro-

[1] This issue is also discussed in the response to comments 37 and 39 on the section 8(a) inventory rule. (42 FR 64586-7, Dec. 23, 1977.)

aing of chlorofluorocarbons into rosol propellant articles intended r export is prohibited after Decemr 15, 1978. Exemptions permitting ocessing for essential uses and for s in FFDCA substances apply equalto both articles intended for domes- use and articles intended for port. The final rule does not prohibeither the manufacture for export the export of articles containing lorofluorocarbon aerosol propelnts. The Agency believes that regution of the processing of chlorofluorrbon propellants into export artiis is adequate to reduce the risk asciated with export of chlorofluororbon aerosol propellants.

EPA decided not to regulate the anufacture and export distribution the unprocessed chlorofluorocarbon ntil Phase II or until such time as PA discovers that increasing quantis of chlorofluorocarbons are being xported for processing abroad into ropellant articles. A major factor in is decision was that the export of he unprocessed substance for propelant uses appears to be minimal, espeially in contrast to the export for ses such as refrigeranta, which are ot subject to the Phase I regulation. PA may also decide to use its authorty under the ozone protection section f the Clean Air Act (42 U.S.C. 7450) o address the export issue. Lastly, a imited ban on the export of the bulk hemical (i.e., only for nonessential ropellant uses) would be difficult o enforce.

The revisions in the rule have been made by adding the references to "export" in the definitions of manufacture, processing, and distribution in commerce, and by adding a new (762.12(b)) which prohibits processing for export.

In addition to the concern about the scope of the export ban, commenters questioned EPA's proposed finding that the export of chlorofluorocarbon propellant articles presents an unreasonable risk of injury to health and the environment of the United States. Commenters stated that the finding was inadequate and that further quantification of the risk is necessary.

EPA disagrees with the comment. While further quantification of all risks associated with chlorofluorocarbons is desirable, it is clear that all discharges contribute to the depletion of the ozone layer, that increased emissions pose correspondingly greater risks, and that discharges anywhere in the world affect health and the environment of the United States. Thus, the Administrator believes that the export of chlorofluorocarbon aerosol propellants presents the same unreasonable risk of injury as domestic use and that steps should be taken to reduce that risk, both to protect the United States' population and environment and to emphasize the United States' concern over domestic and worldwide discharges.

Persons planning to export chlorofluorocarbons should be aware that section 12(b) of TSCA requires exporters to notify the Administrator of any exportation. Procedures for complying with this reporting requirement will be published shortly.

D. REPORTING REQUIREMENTS

The reporting rule is being issued under the authority of TSCA sections 6 and 8. It is intended to monitor compliance with the rule. On the basis of information received in the reports, EPA's Office of Enforcement will be able to direct inspections to those facilities which are most likely to be in violation of the cholorofluorocarbon ban rule. Consequently, facilities which are in compliance with the ban rule will not be required to undergo needless inspection, and EPA resources will not be devoted to unnecessary inspection tasks. In addition, top level management of facilities which manufacture or process chlorofluoroalkanes will be made continually aware of the substance and scope of the chlorofluorocarbon ban rule via the requirement that they personally sign the reports.

In connection with § 712.3, one manufacturer questioned EPA's legal authority to require businesses to submit customer lists. The manufacturer stressed that while TSCA section 8(a) specifies a number of types of information which the Administrator may require to be reported, it makes no mention of customer lists. This argument is not convincing. The legislative history clearly contemplates that the Administrator is to be given access to information necessary for effective enforcement of the Act, and further emphasizes that the types of information described in section 8(a) are only illustrative.

Manufacturers, of course, may make confidentiality claims for their customer lists in accordance with EPA procedures on disclosure of confidential business information, 40 CFR Part 2.

XI. Discussion of the Rule

Some of the reasons for changes from the proposal are discussed in the previous section on Legal Considerations. That discussion should be referred to for a fuller understanding of the revisions.

A. SCOPE

In response to a comment that § 762.1 could be construed ambiguously, the wording has been revised to reflect clearly the intended meaning.

In order for a substance to be subject to this rule, it must be (a) a fully halogenated chlorofluoroalkane, (b) used as an "aerosol propellant," and (c) a "chemical substance" as defined in section 3(2) of TSCA. A fully halogenated chlorofluoroalkane is any molecule which has only chlorine, fluorine, and carbon atoms and which does not have a double or triple bond between two carbon atoms.

B. DEFINITIONS

"Aerosol propellant" means a gas which is used to expel different material from a container. Therefore, if a chlorofluorocarbon is used as an active ingredient, it is not an "aerosol propellant" within the meaning of this rule. If, for example, chlorofluorocarbon F-12 is used to expel chlorofluorocarbon F-113 from the container, only the propellant F-12 would be subject to this regulation. Similarly, if the entire contents in this container consist of one type of chlorofluorocarbon, such as F-12 in a chiller, the product is not subject to Phase I regulation. The nonpropellant aerosol uses will be addressed in the Phase II investigation.

The definitions for "Administrator," "chemical substance," "commerce," "processor," "State," and "United States" have been deleted from the rule. These words have the exact definitions given to them in TSCA (15 U.S.C. 2602), and there is no need to repeat the definitions in the rule.

The definitions for "manufacture," "processing," "distribute in commerce," and "distribution in commerce" also have been omitted. The deletions of the special provisions relating to exports which were included in the proposed rule now make these definitions identical to the ones appearing in TSCA. A discussion of the regulation of exports is found above under Legal Considerations.)

Definitions for "person" and "nonconsumer article" have been added. The definition for "bulk distributor" has been deleted because the term is not used in the final rule.

C. BANS AND EXEMPTIONS

In general, manufacture of chlorofluorocarbons for aerosol propellant uses is prohibited after October 15, 1978. Processing and distribution of unprocessed chlorofluorocarbons are prohibited after December 15, 1978. Exemptions from these general prohibitions are discussed below.

The manufacturing ban (§ 762.11) contains three exemptions. First, manufacture for use in FFDCA substances is not prohibited by this rule. Second, essential uses are exempt. Third, unprocessed chlorofluorocarbons and articles containing chlorofluorocarbon propellants may be imported before December 15, 1978. As discussed at proposal (42 FR 24546), this third exemption alleviates an economic disparity that would otherwise occur in the

treatment of foreign and domestically produced chlorofluorocarbons.

The wording of the third exemption has been changed since proposal to clarify the Agency's intent that the import of chlorofluorocarbons in any form for aerosol propellant uses is prohibited. If EPA exempted the importation of chlorofluorocarbon propellant substances and articles, the effect of this rule could be rendered meaningless by the mass production abroad and importation into the United States of aerosol products for which the manufacture and processing are banned here.

A new § 762.11(a) requires manufacturers of chlorofluorocarbons for aerosol propellant uses to obtain signed statements from their customers that the chlorofluorocarbons are being purchased for aerosol propellant uses permitted by EPA or FDA, or for other uses. These statements will enable the manufacturers to assure themselves that they are manufacturing chlorofluorocarbons in compliance with this rule.

As long as a manufacturer makes chlorofluorocarbons for any propellant use, he must obtain a statement from all his customers (although he need not report nonpropellant customers to EPA under 40 CFR 712.5). While manufacturers who do not make any chlorofluorocarbons for aerosol propellant uses are not required to report to EPA, they are still subject to § 762.11(a). Hence, such manufacturers still have the burden of being able to demonstrate that they are manufacturing chlorofluorocarbons legally.

The processing ban (§ 762.12), as in the proposal, prohibits processing chlorofluorocarbon propellants for domestic or foreign distribution, but it exempts FFDCA substances and essential uses. The final rule also has been changed to prohibit the processing of chlorofluorocarbons for use in pesticide products (as discussed in the Legal Consideration section).

The distribution ban (§ 762.13(a)) prohibits any person from distributing chlorofluorocarbons for processing into aerosol propellant articles after December 15, 1978. Use in FFDCA substances and essential uses are exempted from this section.

The final rule does not regulate the distribution in commerce of articles containing chlorofluorocarbon aerosol propellants (proposed § 762.13(b)). EPA believes that regulation of manufacturing, processing, and distribution in commerce of the unprocessed chemical will be sufficient to eliminate the unreasonable risk to health and the environment.

B. REPORTING

The reporting requirements have been revised in order to reduce and clarify them. They will cover fewer than 100 businesses, and the annual cost of compliance to most of these businesses will range from $30 for one processor to $5,000 for the one of the larger manufacturers.

Annual reports must be submitted by all persons who manufacture and/or process chlorofluorocarbons for aerosol propellant uses subject to TSCA. (Importers are included within the definition of manufacturer by virtue of section 3(7) of TSCA.) If a manufacturer or processor closes his business in 1979, 1980, or 1981, he must submit an annual report for his last calendar year of operations.

Manufacturers reports must list customers who purchase chlorofluorocarbons for aerosol propellant uses, the quantity sold to each of those customers, and the total quantity manufactured for all uses. If none of a manufacturer's customers purchase chlorofluorocarbons for aerosol propellant uses, the manufacturer is not required to submit an annual report to EPA. If a customer purchases chlorofluorocarbons for propellant and nonpropellant uses, the quantities purchased for each category must be indicated. Manufacturers will be able to determine the purpose for which the chlorofluorocarbons are being purchased by examining the signed statements obtained in accordance with § 762.11(c). A manufacturer must submit one annual report covering manufacture in all of his facilities, and the report must conform to the format indicated in the rule.

Processors reports must list the manufacturers or distributors from whom they purchased chlorofluorocarbons, the quantity purchased from each seller, and the quantity processed for each aerosol propellant use. The final rule has been revised so that processors are not required to report the names of their customers. A processor must submit a separate report for each one of his processing facilities, and each report must conform to the format indicated in the rule.

Processors who do not process for aerosol propellant uses are not required to report. If all of the aerosol propellant articles processed by a processor are regulated solely by FDA, the processor does not have to comply with these reporting requirements. If a processor processes both for aerosol propellant uses regulated by FDA and for aerosol propellant uses regulated by EPA, he must report to EPA. Reports submitted to EPA need not specify particular food, drug, and cosmetic uses.

The final rule requires that annual reports be submitted in March of 1980, 1981, and 1982. The 1980 manufacturers report must cover manufacturing from October 16, 1978, through December 31, 1979. The 1980 processors report must cover processing from December 16, 1978, through December 31, 1979. Subsequent annual reports must provide information for the preceding calendar year. Reports must be submitted by registered mail to EPA's headquarters in Washington, D.C. In order to facilitate reading the reports, new provisions require that the reports be written according to a specified format.

ECONOMIC IMPACT ANALYSIS STATEMENT

The economic support document "The Economic Impact of Potential Regulation of Fluorocarbon Aerosols" comprises the economic impact analysis statement required by Executive Order 11821 and OMB Circular A-107.

Dated: March 10, 1978.

DOUGLAS M. COSTLE,
Administrator.

A part 762 is established to read as follows:

OFFICIAL RECORD OF RULEMAKING—FULLY HALOGENATED CHLOROFLUOROALKANES

Section 19(a)(3) of TSCA defines the term "rulemaking record" for purposes of judicial review as follows:

For purposes of this section, the term "rulemaking record" means—

(A) The rule being reviewed under this section;

(B) In the case of a rule under section 4(a), the finding required by such section, in the case of a rule under section 4(b)(4), the finding required by such section, in the case of a rule under section 5(a), the finding required by section 5(f) or 5(a), as the case may be, in the case of a rule under section 6(a), the statement required by section 6(c)(1), and in the case of a rule under section 6(e), the findings required by paragraph (2)(B) or (3)(B) of such section, as the case may be;

(C) Any transcript required to be made of oral presentations made in proceedings for the promulgation of such rule;

(D) Any written submission of interested parties respecting the promulgation of such rule; and

(E) Any other information which the Administrator considers to be relevant to such rule and which the Administrator identified, on or before the date of the promulgation of such rule, in a notice published in the FEDERAL REGISTER.

In accordance with the requirements of section 19(a)(3)(E) quoted above, EPA is publishing the following list of documents constituting the record of this rulemaking. Public comments and submissions made at the rulemaking hearing and in connection with it are exempt from the FEDERAL REGISTER listing under section 19(a)(3) and therefore have not been listed. However, a full listing of these materials is available on request from the Record and Hearing Clerk.

Documents

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Sec.
762.1 Scope.
762.2 Definitions.
762.11 Manufacture: Prohibitions, Exemptions, and Certification Requirements.
762.12 Processing: Prohibitions and Exemptions.
762.13 Distribution in Commerce: Prohibitions and Exemptions.
762.21 Essential Use Exemptions.

AUTHORITY: Toxic Substances Control Act, 15 U.S.C. 2605, 2611.

§ 762.1 Scope.

This part prohibits the manufacture, processing, and distribution in commerce of fully halogenated chlorofluoroalkanes for those aerosol propellant uses which are subject to the Toxic Substances Control Act (TSCA) and lists the exemptions to the prohibitions.

§ 762.2 Definitions.

For the purposes of this Part:

(a) The term "aerosol propellant" means a liquefied or compressed gas in a container where the purpose of the liquefied or compressed gas is to expel from the container liquid or solid material different from the aerosol propellant.

(b) The term "person" includes any natural person, corporation, firm, company, joint venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.

(c) The term "nonconsumer article" means any article subject to TSCA which is not a "consumer product" within the meaning of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2052.

(d) The terms "Administrator," "chemical substance," "commerce," "distribute in commerce," "manufacture," "process," "processor," "State," and "United States" have the same meanings as in 15 U.S.C. 2602.

§ 762.11 Manufacture: prohibitions, exemptions, and certification requirements.

(a) After October 15, 1978, no person may manufacture, except to import, any fully halogenated chlorofluoroalkane for any aerosol propellant use except as follows:

(1) For use in an article which is a food, food additive, drug, cosmetic, or device exempted under 15 U.S.C. 2602; or

(2) For those essential uses listed in § 762.21.

(b) After December 15, 1978, no person may import into the customs territory of the United States any fully halogenated chlorofluoroalkane, whether as a chemical substance or as a component of a mixture or article, for any aerosol propellant use except as follows:

(1) For use in an article which is a food, food additive, drug cosmetic, or device exempted under U.S.C. 15 2602; or

(2) For those essential uses listed in § 762.21.

(c) Every person manufacturing fully halogenated chlorofluoroalkanes for aerosol propellant uses after October 15, 1978, must obtain a signed statement from every person purchasing the fully halogenated chlorofluoroalkanes from him for any use. This statement must specify whether the fully halogenated chlorofluoroalkanes are being purchased (1) for aerosol propellant uses permitted under either 40 CFR Part 762 or 21 CFR 2.125 or (2) for other uses.

§ 762.12 Processing: prohibitions and exemptions.

(a) After December 15, 1978, no person may process any fully halogenated chlorofluoroalkane into any aerosol propellant article except as follows:

(1) For use in an article which is a food, food additive, drug, cosmetic, or device exempted under 15 U.S.C. 2602; or

(2) For those essential uses listed in § 762.21.

(b) After December 15, 1978, no person may process any fully halogenated chlorofluoroalkane into any aerosol propellant article intended for export except as follows:

(1) For use in an article which is a food, food additive, drug, cosmetic, or device exempted under 15 U.S.C. 2602; or

(2) For those essential uses listed in § 762.21.

§ 762.13 Distribution in commerce: prohibitions and exemptions.

After December 15, 1978, no person may distribute in commerce any fully halogenated chlorofluoroalkane for processing into any aerosol propellant article except as follows:

(a) For use in an article which is a food, food additive, drug, cosmetic, or device exempted under 15 U.S.C. 2602; or

(b) For those essential uses listed in § 762.21.

§ 762.21 Essential use exemptions.

The following aerosol propellant uses of fully halogenated chlorofluoroalkanes are essential and exempt from §§ 762.11–762.13:

(a) Mercaptan stench warning devices.

(b) Release agent for molds used in the production of plastic and elastomeric materials.

(c) Flying insect pesticides for use in nonresidential food handling areas except when applied by total release or metered valve aerosol devices, and for space spraying of aircraft.

(d) Diamond-grit spray.

(e) Nonconsumer articles used as cleaner-solvents, lubricants, or coatings for electrical or electronic equipment.

(f) Articles necessary for safe maintenance and operation of aircraft.

(g) Uses essential to the military preparedness of the United States as determined by the Administrator and the Secretary of Defense.

Sec.
712.1 Scope.
712.2 Definitions.
712.3 Reporting requirements for manufacturers of fully halogenated chlorofluoroalkanes for aerosol propellant uses.
712.4 Reporting requirements for processors of fully halogenated chlorofluoroalkanes for aerosol propellant uses.
712.5 General reporting requirements.

AUTHORITY: Toxic Substances Control Act, 15 U.S.C. 2605, 2607.

§ 712.1 Scope.

This Part requires manufacturers and processors of fully halogenated chlorofluoroalkanes for aerosol propellant uses to submit annual reports to the Environmental Protection Agency. It is intended to facilitate the enforcement of Part 762 of this chapter.

[1] The Food and Drug Administration has promulgated separate regulations on use of fully halogenated chlorofluoroalkanes in these articles at 21 CFR 2.125.

§ 712.2 Definitions.

The terms used in this Part shall have the same meanings as in Part 762.2 of this chapter.

§ 712.3 Reporting requirements for manufacturers of fully halogenated chlorofluoroalkanes for aerosol propellant uses.

(a) Every person who after October 15, 1978, manufactures fully halogenated chlorofluoroalkanes for aerosol propellant uses subject to the Toxic Substances Control Act (TSCA) must submit an annual report.

(b) Every annual report submitted by a manufacturer must contain the following information and conform to the following format:

(1) Page one:

(i) Name of business,

(ii) Business address,

(iii) Chief executive officer,

(iv) Addresses of all facilities at which fully halogenated chlorofluoroalkanes are manufactured,

(v) Name, business address, and telephone number of individual most knowledgeable of the contents of this report.

This report covers manufacture of fully halogenated chlorofluoroalkanes for aerosol propellant uses from (date to date).

(2) Page two (and subsequent pages is necessary):

Purchaser	Shipping addresses	Total quantity purchased (in pounds)	Quantity for aerosol propellant uses (in pounds)	Quantity for other uses (in pounds)
List name of customers who purchased for aerosol propellant uses.	(List)	(List)	(List)	(List)

State total quantity in pounds of fully halogenated chlorofluoroalkanes manufactured for all uses for the time period covered by this report.

(3) At the bottom of the last page make the following statement and certification:

I understand that I may assert a claim of business confidentiality by marking any part or all of this information as "TSCA Confidential Business Information" and that information so marked will not be disclosed except in accordance with the procedures set forth in 40 CFR Part 2. I further understand that if I do not mark this information as confidential, EPA may disclose it publicly without providing me notice of an opportunity to object.

I certify that to the best of my knowledge the contents of this report are accurate and complete.

Date _____
Signed _____
Position Title _____

(4) The statement and certification required by paragraph 3 of this section must be signed by the chief executive officer of the manufacturer.

§ 712.4 Reporting requirements for processors of fully halogenated chlorofluoroalkanes for aerosol propellant uses.

(a) Every person who after December 15, 1978, processes fully halogenated chlorofluoroalkanes for aerosol propellant uses subject to the Toxic Substances Control Act must submit an annual report. A separate report must be submitted for each processing facility.

(b) Every report submitted by a processor must contain the following information and conform to the following format:

(1) Page one:

(i) Name of business,

(ii) Business address,

(iii) Chief executive officer,

(iv) Facility address,

(v) Name, business address, and telephone number of individual most knowledgeable of the contents of this report.

This report covers purchases and processing of fully halogenated chlorofluoroalkanes for aerosol propellant uses from (date to date).

(2) Page 2 (and subsequent pages if necessary):

Purchases of fully halogenated chlorofluoroalkanes:

Purchased from and quantity purchased (in pounds)

(List names and business addresses) (list).

Processing of fully halogenated chlorofluoroalkanes:

Use and Quantity (in pounds)

1. Mercaptan mine warning device (list).
2. Release agent.
3. Pesticides.
4. Diamond-grit spray.
5. Electrical/electronic.
6. Aviation.
7. Defense.
8. Food, food additives, drugs, cosmetics, and devices.
9. Other (explain).

(3) At the bottom of the last page make the following statement and certification:

I understand that I may assert a claim of business confidentiality by marking any part or all of this information as "TSCA Confidential Business Information" and that information so marked will not be disclosed except in accordance with the procedures set forth in 40 CFR Part 2. I further understand that if I do not mark this information as confidential, EPA may disclose it publicly without providing me notice of an opportunity to object.

I certify that to the best of my knowledge the contents of this report are accurate and complete.

Date _____
Signed _____
Position Title _____

(4) The statement and certification required by paragraph 3 of this section must be signed by the highest official at the processing facility for which the report is being submitted.

§ 712.5 - General reporting requirements.

(a) Annual reports must be submitted by March 31, 1980, 1981, and 1982. The 1980 manufacturers report must cover manufacturing from October 16, 1978 through December 31, 1979. The 1980 processors report must cover processing from December 16, 1978, through December 31, 1979. Subsequent annual reports must provide information for the preceding calendar year.

(b) Annual reports must be submitted to the Pesticides and Toxic Substances Enforcement Division, Office of Enforcement (EN-342), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

(c) Annual reports must be submitted by registered mail.

[FR Doc. 78-7120 Filed 3-16-78; 8:45 am]

[6355-01]

CONSUMER PRODUCT SAFETY COMMISSION

FULLY HALOGENATED CHLOROFLUOROALKANES AS PROPELLANTS IN AEROSOL CONSUMER PRODUCTS

Commission Action in Response to the Environmental Protection Agency's Ban

In this document, the Consumer Product Safety Commission (CPSC) announces that, in view of the Environmental Protection Agency's (EPA) final rules appearing elsewhere in this issue of the FEDERAL REGISTER prohibiting almost all of the manufacture, processing, and distribution in commerce of fully halogenated chlorofluoroalkanes (chlorofluorocarbons) for those aerosol propellant uses which are subject to the Toxic Substances Control Act (TSCA), banning action by the CPSC is unnecessary.

Previously, the Commission had preliminarily concluded that aerosol consumer products which use certain chlorofluorocarbon propellants should be banned because they present an unreasonable risk of injury to consumers from the destruction of the stratospheric ozone layer and no feasible consumer product safety standard would adequately protect the public. The Commission's staff was directed to work with EPA and the Food and Drug Administration (FDA), which had announced their intentions to phase out the non-essential uses of fluorocarbons in products under their jurisdiction. Subsequently, the Commission reviewed the ban that was proposed by EPA and determined that banning action by the Commission was unnecessary at that time (42 FR 24550, May 13, 1977).

Except for those products that have been deemed by EPA to be "essential," the final EPA ban applies to all products using these chlorofluorocarbons as propellants to expel other materials from a container that are subject to the jurisdiction of the Commission. After considering the terms of the final ban issued by EPA, the Commission still believes that it is not necessary for it to take any banning action in addition to that already taken by EPA.

The Commission did, however, issue a final rule (16 CFR Part 1401, 42 FR 42780, August 24, 1977), effective February 20, 1978, that requires labeling of consumer products containing these chorofluorocarbon propellants and requires the manufacturers of such products to submit product identifying information to the Commission. This labeling rule is somewhat broader than the EPA ban in that it applies to "essential," as well as nonessential products and to products in which the propellant is the only substance expelled.

The Commission's staff is continuing to cooperate closely with the EPA and the FDA through the Interagency Chlorofluorocarbon Work Group (a committee including EPA, FDA and CPSC representatives) as it explores the possible regulation of certain chlorofluorocarbons in non-aerosol uses.

Dated: February 23, 1978.

SADYE E. DUNN,
Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 78-7121 Filed 3-16-78; 8:45 am]

United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Washington, D.C. 20520

February 2, 1987

UNCLASSIFIED
~~(LIMITED OFFICIAL USE attached)~~

To: EPA - Bill Long
NASA - Bob Watson
NOAA - Joe Fletcher
Commerce - Michael T. Kelly
USTR - Bruce Wilson
DOE - Ted Williams
DPC - Ralph Bledsoe
OMB - Randy Davis
CEQ - Coleman Nee ✓
EB/TDC/OT - Kevin McGuire
EB/IFD/OIA - Sharon Villarosa
L/OES - David Colson
L/EBC - Gerald Rosen
E - Martin Bailey

From: OES/E - John H. Rouse, Acting JR

Subject: Ozone Layer Protection Protocol Negotiations

The next round of negotiations for a protocol to control chemicals which deplete stratospheric ozone will be held in Vienna February 23-27. Protection of the ozone layer is a complex and difficult issue involving diverse interests of many agencies. We want to be sure those interests are reflected in our preparations for the negotiations.

Meetings

Representatives of all interested agencies will meet:

Tuesday, February 3, 2:00 p.m., Room 7835 attendees

Thursday, February 12, 9:30 a.m., Room 7835

Thursday, February 19, 2:30 p.m., Room 1105

Please arrange for appropriate representation from your agency for these meetings.

On February 3, we will review the status of work in preparation for the negotiations, air any concerns, and task additional work as appropriate. On February 12 we will review the draft position paper.

The trade work group will also meet on Feburary 5 with representatives of interest groups (see enclosed memo).

Delegation

We need to review the size of the U.S. delegation, in view of requirements of the Office of International Conferences and of the disportionate size of our group in Geneva. For each individual your agency believes should be a member of the delegation, please provide by Friday, February 6 a letter from a policy-level official of your agency to Ambassador Negroponte naming the individual, title, and justification for agency representation on the delegation. This letter will be required for accreditation of any delegation member.

Enclosures:

Nairobi 2786
State 16544
86 Paris 56660
Benedick 12/1/86 plenary statement
U.S. proposed protocol text
Negroponte testimony, 1/28/87
Potter testimony, 1/28/87
Butcher trade meeting memo, 1/29/87
Circular 175, 11/28/86

OES/ENH:SButcher
2/1/87 2471T

STRATOSPHERIC OZONE PROTOCOL NEGOTIATIONS

Pre-Geneva Negotiations

- Convention to Protect Ozone Layer (March 85)
- International Workshops
- Industry Policy Shift
- Canadian Protocol Text
- U.S. Position (first step; move down emissions curve; establish review/adjustment process)

Geneva (Dec. 1-5, 1986)

- Focus on general principles/approaches
- Consensus toward narrow scope freeze at current level
- Little discussion of longer-term objectives and process (including specific texts)
- Differences among U.S., Canada, Nordics, EC, Japan

Post Geneva

- U.S. focus on building international support/awareness for resumed negotiations, and sharing views
- Continuing examination of trade aspects, other control options

Vienna Meeting (Feb. 23-27, 1987)

Objectives

- Promote expanded debate on key protocol components
- Assess flexibility/attitudes of broader range of countries
- Ensure full discussion of longer term (reduction and process)
- Establish points of consensus and differences
- Use U.S. text to press for meaningful agreement

Issues

- Scope of chemical coverage*
- Calculation of allowable emissions* (e.g., GEL; adj. production)
- Allocation of allowable emissions (e.g., Canadian approach; U.S. "polluter pays" approach)
- Timing and stringency of controls (e.g., near term freeze* at current levels; longer term reduction)
- Scientific assessment mechanism*
- Treatment of small or non-producers* (developing countries/ equity argument)
- Treatment of non-parties* (including trade restrictions)
- Future negotiating schedule, and diplomatic conference*

*Could make substantial progress in Vienna

Drafting Group on Stratospheric Ozone for DPC
Energy and Natural Resources Working Group

I. GOAL

A paper for submission to the Working Group and ultimately the DPC which (a) states where the U.S. is with respect to science, law, international negotiation, Congressional, environmental regulation, and industrial views regarding stratospheric ozone and current agreed Administration policies, and (b) proposes possible policy options for any future action by the Administration.

II. PROCESS

A drafting group with appropriate representation will prepare a paper for the submission to the Working Group and its ultimate submission to the DPC. The initial draft and the necessary drafting service will be provided by OMB.

III. MEMBERS

The members of the drafting group should include at least the following and their agencies:

Chairman- DPC Ralph Bledsoe or designee

who else? — USTR? Marian Borell Nelson

OMB	Dave Gibbons; _____ draftor
CEA	Steve Decanio
CEQ	Jackie Shaeffer
OPD	Jan Mares
EPA	Craig Potter (Air and Water)
	Jack Campbell (Policy)
State	Richard Benedick
Commerce	Mike Kelly (ITA)
	J.R. Spratling (NOAA)
Energy	Ted Harris
Interior	~~Marty Smith~~ Becky Dunlop
NASA	Bob Watson
Justice	_____

IV. PROPOSED SCHEDULE

1. Organization/shaping meeting of group of one hour duration on Thursday or Friday, March 26 or 27 to discuss one page list of policy options prepared by OMB.

2. Initial draft paper submitted to working group by Wednesday afternoon, April 1.

3. One and one half hour discussion of draft Friday, April 3.

4. Redrafting of memorandum based on meeting and circulation to group on Monday, April 6.

5. Final discussion of paper on Tuesday, April 7 8:00 a.m.

6. Rework and submission of paper to DPC working group for their meeting on April 14.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

ROUTE SLIP

TO Vicki	Take necessary action	☐
	Approval or signature	☐
	Comment	☐
	Prepare reply	☐
	Discuss with me	☐
	For your information	☐
	See remarks below	☐
FROM Barbara Gutierrez	DATE 4/17/87	

REMARKS

Attached are some EPA Qs and As on ozone for your review. Please let me know if you have any comments by COB Monday or Tuesday morning —

Thanks —

Barb

OMB FORM 4
Rev Aug 70

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 15 1987

OFFICE OF
EXTERNAL AFFAIRS

MEMORANDUM

SUBJECT: EPA responses to Rep. Dingell's and Waxman's questions on stratospheric ozone

FROM: Steadman M. Overman
Director
Office of Legislative Analysis

TO:

Name	Agency	Telephone	Transmission
Lisa Lindeman		377 4264	377-0512
Barbara Moore	(NOAA/DOC)	443-8845	FACS. 443-5167
Michael Kelley	(DOC)	377-0614	FACS. 377-5270
Edwin Shykind	(DOC)	377-4694	FACS. 377-5270
Ted Williams	(DOE)	586-2061	FACS. 586-2707
Ted Harris	(DOE)	586-5659	FACS. 586-2707
Bob Watson	(NASA) Lynn Murphy	453-1681	FACS. 472-7634
Pep Fuller	(USTR)	395-7203	FACS. 395-3911
Marty Smith	(DOI)	343-1632	FACS. 289-4714
Suzanne Butcher	(DOS)	647-9312	FACS. 647-1106
Amy Salzman	(DOJ)	633-4361	FACS. 633-4495
Coleman Nee	(CEQ)	395-5750	OMB HAND CARRY
Jan Mares	(OPD)	456-2752	OMB HAND CARRY
Stephen DeCanio	(CEA)	395-6982	OMB HAND CARRY
Donald Fox Vicki Mastrman	(DoD)	653-1273	

The Office of Management and Budget has requested that we solicit your comments on the attached responses.

Please provide any comments to Barbara Gittleman (395-6827) at OMB no later than C.O.B. FRIDAY, 17 April 1987.

Attachment

cc: Barbara Gittleman
OMB/FACS. 395-3130
Tele. 395-6827

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE ADMINISTRATOR

Honorable John D. Dingell
Chairman, Subcommittee
on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington D.C. 20515

Dear Mr. Chairman:

I am writing in response to your letters of March 4 and March 13. In those letters you asked several questions concerning CFC's and the U.S. position in the ongoing negotiations on protection of the ozone layer. Enclosed is our response to your questions.

Thank you for your continuing interest in this important issue.

Sincerely,

Lee M. Thomas

Enclosure

cc: Honorable Charles A. Bowsher
Comptroller General, GAO

ISSUES RAISED IN COVER LETTER

Issue

One area of concern is the trade area. A strong and effective trade provision is important. But to be workable and effective, it must be consistent with other U.S. policies and trade practices, unless there is some basis for deviation. I do not have a feeling that there has been a coordinated development of such a provision for this protocol.

Response

EPA, Department of State, Office of U.S. Trade Representative and Department of Commerce have expanded their efforts to analyze trade issues related to action to limit ozone-modifying chemicals. These activities are described in response to question 2 below.

Issue

I am also concerned that the Environmental Protection Agency (EPA) has not received sufficient input from the user industries that could be severely affected by any significant reduction requirements or the trade provisions of the protocol.

Response

EPA has maintained an extensive effort to obtain input from user industries. We fully recognize the need to understand the impact of any reductions and trade measures on user industries. To assist us in evaluating options we have held numerous meetings over the past year with representatives of all key industries. A partial list of these meetings is shown in Exhibit 1. We have also initiated a series of technical studies

analyzing the engineering feasibility and cost impacts of possible controls. These studies have and will be reviewed by relevant industry groups. (See Exhibit 2) Finally, we are discussing joint research projects with key user industries interested in evaluating the use of chemical substitutes in their applications.

Issue

Incidentally, your reply to my question 7(a) states that the "Court Order requires a proposal by May 1, 1987, and a final rule by November 1, 1987." However, the actual wording of the Order does not seem to support that statement. It states:

> 2. Not later than May 1, 1987, the Administrator of EPA shall sign a Federal Register notice proposing regulatory action of CFCs or presenting a basis for a proposed decision to take no action.
>
> 3. Not later than November 1, 1987, the Administrator of EPA shall sign a Federal Register notice promulgating regulation or announcing a final decision to take no action.

A "no action" decision at either time is not a rule.

Exhibit 1

PARTIAL LIST OF MEETINGS WITH INDUSTRY TO DISCUSS
STRATOSPHERIC OZONE PROTECTION ACTIVITIES

MAJOR DOMESTIC WORKSHOPS

March 6-7, 1986;
EPA Workshop (over 130 attendees)

June 16-20, 1986;
EPA/UNEP Effects Conference (over 300 attendees)

July 23-24, 1986;
EPA Workshop (over 130 attendees)

October 14, 1986;
State Dept/EPA meeting (over 25 attendees)

February 18, 1987;
Facilitated Regulatory options review (30 attendees)

April 2, 1987
Facilitated Regulatory Options Meeting (10 attendees)

April 6, 1987
Facilitated Trade Issues Meeting (10 attendees)

WORKING MEETINGS WITH INDUSTRY REPRESENTATIVES (partial list; -- end of 1986 and -- 1987 to date)

September 4, 1986
Chemical Manufacturers Assoc. representative

October 16, 1986
Meeting with chemical producer

October 20, 1986
Meeting with air conditioning, refrigeration representatives

October 29, 1986;
Halon industry representatives (20 attending)

November 3, 1986
Meeting with Motor Vehicle Manufacturers Association (8 attendees)

November 4, 1986
Meeting with Electronics Assocaition (4 attendees)

November 6, 1986;
Halon industry representatives (30 attending)

November 14, 1986
Meeting with Chemical Producers (6 attendees)

December 3-5, 1986;
National Fire Protection Association Halon 1301 Technical Committee (40 attending)

December 8, 1986
Briefing for Frozen Food Institute

December 8, 1986
Briefing for Single Service Institute

December 8, 1986
Briefing with National Association of Manufacturers

January 17-18, 1987;
Fire Suppression System Association annual meeting (300+ attending)

January 29, 1987;
American Chemical Society Fluorine meeting (500+ attending)

February 4-5, 1987;
Rigid Foam industry representatives (10 attending)
February 11, 1987;
Thomas breakfast meeting with electronics industry (50 representatives)

February 19-20, 1987;
Experts Panel-Chemical Substitutes (15 experts from 5 nations)
February 20, 1987;
Halon industry (15 representatives)

March 3, 1987;
25 group heads from ASRAE

March 10, 1987;
Representatives from plasics industry (15 attendees)

March 11, 1987;
Motor Vehicle Manufactures Association (12 representatives)

March 17, 1987;
Automobile Importers Associations (20 representatives)

March 26, 1987;
Halon manufacturers representatives (10 attending)

April 8-9, 1987;
Meetings with Motor Vehicle Manufacturers

Exhibit 2

EPA should also list studies additional if possible (skyhook).

LIST OF TECHNICAL ENGINEERING COST STUDIES

Completed and On-going Studies	Contractor
1. Evaluation of Potential Ozone Depleting Substance Emissions and Controls.	
A. Flexible Polyurethane Foam Industry	Radian
B. Rigid Foam Industry	Radian
C. Retail Food Store Refrigeration	Radian
D. Mobile Air-Conditioning Industry	Radian
E. Industrial Solvents Use	Radian/ICF
F. Halons, Banks and Emissions	Industrial Economics, Inc.
G. Sterilant Gas	Radian/MRI
H. Liquid Food Freezing	Radian
2. Control Technology Overview Report, CFC-11 Emissions from Flexible Polyurethane Foam Manufacturing	Radian
3. Control Technology Overview Report Emissions From Rigid Foam Manufacturing	Radian
4. Chlorofluorocarbon Chemical Substitutes	Radian and Consultants
5. Emission Controls and Potential Alternatives for CFC-113 and Methylchloroform in Solvent Cleaning Operations	MRI
6. Analysis of Costs of Control Options - A Computer Database (Draws from above studies)	ICF
OTHER STUDIES	
7. Social Cost of Technical Control Options to Reduce Emissions of Potential Ozone Depleters in the United States	Rand
8. Product Uses and Market Trends for Potential Ozone Depleting Substances 1985 - 2000	Rand

Response

We agree that the district court order setting forth the CFC decision-making schedule does not require the Agency to necessarily adopt regulations. The court order requires that by November 1, 1987, EPA either promulgate regulations controlling CFCs or announce a final decision to take no action.

QUESTIONS RAISED IN ATTACHMENT

TRADE

Question 1

Re the draft article's ban or restriction on "imports of products containing substances controlled by this protocol from any state not party to this protocol...":

(a) What are the policy implications for the U.S. (of restricting imports of Korean automobiles with CFCs) beyond the narrow confines of this protocol? (b) Is it likely that the U.S. would want to impose such a ban or restriction, taking into consideration other interests in that country (Korea)? (c) What happens if the South Korean manufacturers import the cars... and arrange for (air conditioning) assembly and charge in the U.S., as is done today by several foreign manufacturers?

Response

(a) Import restrictions for environmental or safety reasons are allowable under the GATT and therefore restrictions pursuant to the international protocol would be a legitimate policy option for the U.S. These trade provisions have been developed in close cooperation with the State Department and are therefore consistent with other U.S. foreign policy goals.

With respect to South Korea specifically, we would anticipate that South Korea would initially object to any U.S. restrictions on the importation of Korean automobiles pursuant to an international protocol. However, we believe that, rather than becoming a major irritant in bilateral relations, the restrictions could produce positive results. Given the importance of the U.S. market to both Hyundai and Daewoo (the two Korean companies currently exporting automobiles to the U.S. market), we believe that U.S. restrictions would create a strong incentive for the Korean manufacturers to limit their use of CFCs in order to maintain access to the U.S. market. Such an outcome would be positive both from the perspective of bilateral relations and U.S. and global environmental policy and would be consistent with one of the major objectives of the protocol itself, i.e. to provide an incentive for non-parties to limit their use of CFCs.

(b) We do not believe that the imposition of restrictions on imports of Korean automobiles would be detrimental to any U.S. interest in Korea. As described above, we do not believe that such restrictions would necessarily result in a closure of the U.S. market to such imports but rather in the Korean manufacturers modifying their product to suit the requirements of the U.S. market.

(c) If Korean manufacturers were to arrange for the assembly and charging of automobile air conditioners in the U.S. (a production option which is also currently available to them), the use of CFCs in the air conditioning systems charged in the US would be subject to the availability of CFCs in the U.S. market. We would anticipate that, under the protocol, the availability of CFCs would decrease and that, as a result, both domestic automobile manufacturers

and foreign manufacturers charging air conditioners in the U.S. might have an incentive to develop alternative technologies or chemical substitutes for such operations. Such a development would clearly advance the objectives of the protocol.

Question 2:

"I am also concerned about the exception which appears throughout this draft article on trade. It appears to allow a nonparty to avoid the obligations of the protocol and continue to enjoy trade with parties, merely because that party is in partial compliance with the protocol. That does not appear fair, nor does it seem consistent with the objectives of the protocol?"

Response:

As noted, the draft protocol provides an exception to the import restrictions for certain non-party countries. The exception would not apply to any country in "partial compliance." It is our intention that only those countries which can demonstrate full compliance with the articles on Control of Trade would benefit from this exception. These articles, more than any others, would have the greatest direct effect on the reduced use and emissions of CFCs, which is the main objective of the protocol. The intention of this exception is to cover the case of states which would be excluded for joining the protocol (eg, Taiwan, South Africa) and possibly those countries that consume so little CFC per capita that restrictions would be unreasonable or unfair in light of essential uses.

Question 3:

What measures could constitute a "restriction" on imports? Are we contemplating tariffs or some other restrictions?

Response:

We are currently assessing a variety of mechanisms to control imports, including tariffs, imports fees, testing, certification and inspection requirements, and quotas. As part of this review, we are attempting to identify whether certain mechanisms are better suited than others for controlling imports of particular products. Our analysis on this question will continue during the next several months.

Question 4:

The draft article calls for "standards" for applying measures "uniformly by all parties." Does that also mean that all products commonly produced by one or more parties would be restricted in a uniform manner by all parties?

Response:

Paragraph II of the Trade Article calls for the parties to develop, in an annex, standards for applying the restrictions in this paragraph uniformly by all parties. We view this to mean that the annex would set the parameters for Parties' application of the restrictions in this paragraph; i.e., we envision this to be a set of guidelines, rather than a set of rules. We will attempt to clarify this point during the next negotiating session.

Question 5:

"Is the article adequate from the standpoint of U.S. industry and jobs? How will it impact on U.S. firms that have dealings with non-party countries, including developing countries?"

Response:

Because the United States is a small importer of CFC bulk chemicals (only 3 percent of domestic consumption) the ban of such imports from nonparties as called for in paragraph 1 of Article on Control of Trade, would have a minimal effect on U.S. domestic industries and jobs. To the extent there is an effect at all, U.S. industries may marginally increase production and job creation.

With regard to the restriction or banning of imports of products containing CFCs (such as automobiles, air conditioners, refrigerators) the effect of import restrictions or bans should have a greater effect than for CFC bulk chemicals, if only because imports of these products represent a larger share of the U.S. market. Import restrictions or bans of these products should have a positive effect on domestic producers. At the same time, domestic prices of these products may rise. In the real world, however, the major producers of these products are in the OECD countries and are expected to sign the protocol. Exports of these countries to the U.S., therefore, would not be restricted as would those of non-parties to the protocol. Therefore, the effect on U.S. industries and jobs may be minimal.

Regarding dealings by U.S. firms with non-party countries, including developing countries, U.S. firms would be subject to the protocol's ban on import of CFC bulk chemicals from non-parties as well as the restriction or ban

of products containing CFCs (eg, automobiles, furniture). It is important to note that a primary purpose for restricting imports from nonparties is to create an incentive for them to join the protocol. The greater the number of parties to the protocol, the more global production of CFC related products that will be covered under the international agreement. This would minimize the effects of the agreement on US industries and consumers relative to those in other countries.

Qualitative evaluations of the protocol's impact on U.S industries, jobs and the like are currently underway.

HALONS AND THE DEFENSE DEPARTMENT

(The response below is being provided directly by the Department of Defense to Representative Dingell. It is followed by a comment by EPA.)

Question 6.

DoD Comment on "draft article on trade":

The draft article on trade establishes provisions for interacting with countries which do not sign the international protocol. These provisions are not inconsistent with DoD policy. DoD will defer to the Departments of State and Commerce for the specific language contained in the draft protocol.

Question (a):

What are the DoD's unique requirements?

DoD response:

Fire fighting systems for
- Shipboard operations
- Aircraft systems
- Tank/Personnel Carrier systems
- Hardened aircraft shelters

Command, Control and Communication Systems
- Computer Centers
- Telephone Switching stations

One of a kind trainers
- Aircraft simulators

(Additional requirements may be identified when services provide information on Halon use to EPA in April 1987.)

Question (b):

What is the "national CFC policy"?

DoD response:

EPA is in the process of formulating a national CFC policy. The agency is gathering information from manufacturers, distributors and users of CFCs. At this time, DoD is gathering use data on Halons for EPA.

Question (c):

In the above reply and elsewhere in the March 2 reply (e.g., question 6(C)), EPA refers to regulatory actions or options. What "regulatory options" does EPA contemplate? Will they require legislation? How can these options provide special exceptions for DoD needs unless the final protocol provides such an escape? Is such an escape desirable?

DoD response:

DoD is cooperating with EPA in their on-going efforts to develop regulatory options.

DoD and EPA are discussing options for including Halons in the international protocol. These options explore ways to grandfather Halons for existing and future military mission critical uses until suitable substitutes are found. We prefer that each location on site specific use of Halons not undergo a lengthy permit process (like RCRA PartB permits), since mission readiness would be impaired.

Question (d):

Please provide the date of the meeting and the identity of the persons attending. What did DoD say at that meeting?

DoD response:

Date: February 12, 1987 Location: Pentagon

Attendees	Organization
Dr. Donald L. Fox	DoD-ODASD (E)
Dr. Stephen O. Andersen	EPA
Dr. Michael J. Ryan	ICF (EPA Contractor)
Ms. Laura K. Greninger	Army-DAEN-ZCE
Mr. Carl Zillig	Navy-CNO (OP45)
Mr. James P. Wright	Navy-NAVFACHQ
Ms. Barbara Sparks	Navy-NAVFAC
Mr. Bruce Unkel	Navy-NAVSEA
Mr. Robert Darwin	Navy-NAVSEA
Mr. John Merold	Navy-NAVSEA
Mr. William M. Stem	Navy-NAVSEA
Mr. Gordon LeQuire	Navy-NAVAIR
Mr. Dan Quagliarello	Navy-NAVAIR
Mr. Tom Scarano	Navy-NAVSBA
Ms. Laurie Huber	Marines-HQMC(LFL)
LtCol Steve TerMaath	Air Force-SAF/MIQ
Maj. Marti U. Bischoff	Air Force-HQUSAF/LEYSF
Maj. Edward W. Artiglia	Air Force-HQAF/SGP
Mr. William D. Goins	Air Force-HQUSAF/LEEV
Mr. Fred Walker	Air Force-HQUSAF/LEEEV
Mr. J. D. Williams	Air Force-HQUSAF/LEEEV

Meeting Summary

EPA presented an overview of the role of chlorofluorocarbons on stratospheric ozone depletion with the discussion focusing on Halons. EPA representatives requested information from the military services on the use and releases of Halons.

DoD has requested the military services to provide Halon use information to EPA in early April 1987.

Question (e):

The above EPA reply lists several EPA suggestions. Does the DoD agree with them?

DoD response:

The Department of Defense supports efforts to protect the environment and EPA's efforts to prevent stratospheric ozone depletion. DoD will incorporate appropriate substitutes for Halons in fire protection systems when they are able to meet mission critical applications. To the same degree as industry, DoD will take steps to decrease the non-firefighting releases of Halons in the future.

At the present time, DoD has mission critical uses for Halon to protect personnel and equipment. DoD and EPA are cooperating to ensure that regulatory options relating to fire protection would not jeopardize the survival of military personnel or the operation of critical equipment.

EPA Comment on Halons Question:

EPA's goal is to ensure that any future regulatory action on Halon emission reduction to protect stratospheric ozone is also equitable to all users and recognizes military mission critical requirements. EPA has discussed control suggestions with DoD that were flexible to allow the evolution of an effective, military mission compatible policy.

EPA and DoD have common concerns in the control of Halons. Both want an effective and timely policy and a set of procedures to limit halon releases if necessary to protect the ozone layer. DoD does not want regulatory controls relative to fire protection which hinder the operation of critical equipment