DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 201, 369, 501, 740, and 801

[Docket No. 93N–0442]

Warning Statements for Products Containing or Manufactured With Chlorofluorocarbons and Other Ozone-Depleting Substances

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule; opportunity for comment.

SUMMARY: The Food and Drug Administration (FDA) is issuing interim regulations governing warning statements for products containing or manufactured with chlorofluorocarbons (CFC's) and other ozone-depleting substances. The amendments prescribe specific warning statements and additional labeling statements for physicians and patients. These additional statements direct patients to consult their physicians before discontinuing use of a prescription medical product because of concerns about the product's effect on the environment and public health. The interim rule also provides warning statements for over-the-counter (OTC) drug and device products and directs patients to consult their physicians, health professional, or suppliers with questions about the products. In addition, the interim rule revises certain regulations concerning foods, cosmetics, and animal foods in a self-pressurized container with a CFC propellant in order to be consistent with current statutory requirements. FDA is issuing these regulations as an interim rule with opportunity for public comment.

DATES: Interim rule effective May 17, 1996; comments by August 1, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION:

I. Background

On February 11, 1993 (58 FR 8136), the Environmental Protection Agency (EPA) issued final regulations requiring, among other things, a warning statement on all products containing or manufactured with specific ozone-depleting substances. In general, the EPA regulations require each container or product containing or manufactured with CFC's, halons, carbon tetrachloride, and methyl chloroform to bear the following warning statement (58 FR 8136 at 8165):

> Warning: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

EPA issued the rule under section 611 of the Clean Air Act (42 U.S.C. 7671(j)), which requires the warning statements on all products containing or manufactured with CFC's on or after May 15, 1993. In promulgating the rule, EPA noted that several comments had argued that certain prescription medical products, such as metered-dose inhalers, should be exempt from the labeling requirements because they are essential to the health of patients. The comments indicated that a warning statement might lead some patients to avoid their medication because of concerns about the product's effect on the environment or alarm over the words ''harms public health.'' EPA stated that it understood the importance of such products to patients as well as the need to ''tailor the labeling requirement to avoid unduly alarming patients,'' but also stated that it lacked the authority to exempt prescription medical products from the labeling requirement (see 58 FR 8136 at 8155). Consequently, EPA indicated that the statutorily required warning statement could appear on supplemental printed material intended for physicians rather than patients, provided that the supplemental printed material intended for patients contain similar warning language without the words ''warning'' and ''harms public health'' (see 58 FR 8136 at 8156). EPA also indicated that manufacturers of prescription medical products could supplement this information with additional information for patients. EPA anticipated that FDA would provide the specific additional language (see 58 FR 8136 at 8156). On June 29, 1993 (58 FR 34812, corrected on July 29, 1993, 58 FR 40656), FDA published a notice in the Federal Register setting out alternative labeling warning language designed not to cause undue patient alarm. The warnings were essentially identical to the warnings contained in this interim rule. As part of the notice, FDA requested comments about CFC warning statements. These comments are summarized and responded to in section III of this preamble.

Since 1977 (42 FR 22018, April 29, 1977), FDA has required, with a few exceptions, that OTC human drug and nonrestricted device products containing CFC propellants be labeled with a warning (21 CFR 369.21 and 801.425). In addition, FDA established regulations in §§ 101.17(c), 501.17(c), and 740.11(c) (21 CFR 101.17(c), 501.17(c), and 740.11(c)) that required that the package of a food, animal food, or cosmetic in a self-pressurized container in which the propellant consists in whole or in part of a fully halogenated CFC bear the following warning statement:

> Warning: Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.

These regulations also provided requirements for placement and conspicuousness of the warning statement. The required warning statement applied only to self-pressurized containers that use CFC as a propellant. For example, for foods, the use of the warning statement was not required when the CFC was used as a stabilizer in food toppings and spreads (§ 101.17(c)(3)).

Since 1978 (43 FR 11301, March 17, 1978), FDA has prohibited the use of CFC propellants in most products it regulates (21 CFR 189.191, 300.100, 500.49, 700.23, and 801.417), except those listed as essential uses of CFC's in § 2.125 (21 CFR 2.125). Nonessential uses, which were prohibited by the 1978 final rule, included CFC use as a propellant in self-pressurized containers for foods and cosmetics. The prohibitions against nonessential uses of CFC's, set out in § 2.125(c), provide that ''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 * * *.'' Section 2.125(e) exempts certain essential uses of CFC's from the adulteration and misbranding provisions of § 2.125(c). Further, § 2.125(f) specifically provides for the filing of a petition in accordance with 21 CFR part 10 to provide for the listing of additional essential uses so as not to subject the new use to the adulteration and misbranding provisions in § 2.125(c).

FDA notes that all of the essential uses of CFC's exempted from the adulteration and misbranding provisions of § 2.125 that are listed in § 2.125(e) apply to drug products. No

essential uses of CFC's for foods, cosmetics, or animal foods in self-pressurized containers have been identified.

II. Description of the Interim Rule

This interim rule describes the warning statements that should accompany human prescription drug, biologic, and device products, and restricted device products (hereafter referred to as ''prescription human medical products''), OTC drug and device products, and animal drug products that contain or are manufactured with CFC's, halons, carbon tetrachloride, methyl chloroform, and any other class I ozone-depleting substance designated by the EPA Administrator. (A list of class I ozone-depleting substances can be found in 40 CFR part 82, appendix A to subpart A, and any later EPA rulemaking adding other ozone-depleting substances.)

The interim rule provides two options for labeling prescription human medical products and OTC drugs and devices. The first option is EPA's warning statement:

Warning: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

The second option for prescription human medical products contains FDA's additional language for the alternative warning statements. These warning statements are intended for physician labeling and patient labeling.

The warning for the physician package insert would be used in conjunction with an alternative warning statement that would appear on patient labeling as stated in the EPA final regulation (58 FR 8136 at 8166). These alternative warning statements would be written so that patients do not cease using their medications because of concerns over the products' effect on the environment or alarm over the words ''harms public health'' without first consulting their physicians. Instead, patients would be able to discuss their concerns with their physicians or, in the case of OTC drug or device products, another health professional or suppliers, and, if they wish, consider the use of alternative treatments. Also, physicians would be alerted to products that contain ozone-depleting substances. FDA believes that these warning statements will enable patients, physicians, pharmacists, other health professionals, and suppliers (in the case of devices) to make informed decisions.

Animal drug products manufactured with CFC's or other ozone-depleting products are required to use EPA's warning statement because the optimal alternative labeling statement is restricted to human medical products.

A. Prescription Human Medical Products

For prescription human drug products, new § 201.320 (21 CFR 201.320) provides both the EPA warning statement and FDA's alternative warning statements. New § 801.443 (21 CFR 801.443) provides the same two options for prescription and restricted devices. A biological product regulated as a drug or a device would use whichever labeling applies to the particular biological product. Under new §§ 201.320 and 801.443, all prescription drug and device products and restricted devices containing or manufactured with CFC's, halons, carbon tetrachloride, methyl chloroform, or any other class I ozone-depleting substance designated by the EPA Administrator shall use the EPA warning statement or specified alternative warning statements. For the first option for a warning statement, new §§ 201.320(a) and 801.443(a) provide the EPA warning statement quoted earlier in this preamble.

Under new §§ 201.320(a)(2) and 801.443(a)(2), the warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling, and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase.

For the second option, new §§ 201.320(b)(1) and 801.443(b)(1) provide FDA's alternative warning statements for supplemental printed materials intended for physicians and for patients. For patient labeling, the warning statement would appear on the product, its packaging, or supplemental printed material intended for the patient and would read as follows:

Note: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or name of other class I substance, if applicable].

This product contains [or is manufactured with, if applicable] [*insert name of substance*], a substance which harms the environment by destroying ozone in the upper atmosphere.

Your physician has determined that this product is likely to help your personal health. USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY YOUR PHYSICIAN. If you have any questions about alternatives, consult with your physician.

These statements are designed to explain that the Clean Air Act requires the warning statement, but that patients should continue to use the prescription medical product unless instructed otherwise by their physicians. The labeling for the physician would be placed on the physician package insert after the ''How supplied'' section on the label describing the special handling and storage conditions.

For the package insert for the physician, the warning statement would state that:

Note: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [*or name of other class I substance, if applicable*].

Warning: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

A notice similar to the above WARNING has been placed in the information for the patient [or patient information leaflet, if applicable] of this product under Environmental Protection Agency (EPA) regulations. The patient's warning states that the patient should consult his or her physician if there are questions about alternatives.

For the second option, for the alternative placement on supplemental printed material described in new §§ 201.320(b) and 801.443(b), the interim rule specifies a particular location for the warning statement intended for the physician; provided, however, that a person places the statement intended for the patient on the product, its packaging, or supplemental printed material for the patient. The warning label shall be clearly legible and conspicuous on the product, its immediate container, or other labeling as to render it likely to be read and understood by consumers under normal conditions of purchase. FDA further advises all parties that new §§ 201.320 and 801.443 do not replace or relieve a party from the requirements under 40 CFR part 82.

FDA notes that EPA's regulations (58 FR 8136 at 8166 (40 CFR 82.108(c))) state that, for prescription human medical products that FDA finds to be essential for patient health, the warning statement may be placed in supplemental printed material intended to be read by the prescribing physician, as long as the alternative statement is placed on the product, its packaging, or supplemental printed material intended to be read by the patient at time of purchase. The agency believes that new §§ 201.320 and 801.443 are consistent

with these EPA requirements. However, FDA declines at this time to determine which products are essential for public health. The Clean Air Act requires that the warning labels be on all products containing or manufactured with CFC's on or after May 15, 1993. FDA believes it would be impractical and unnecessary to engage in case-by-case determinations of which medical products are essential to public health before permitting alternative warning statements. Thus, until FDA can establish criteria and make individualized determinations as to whether a drug is essential to public health, the most prudent course of action is to presume, for purpose of the warning statement, that all prescription human medical products are essential to public health.

B. OTC Drug and Device Products

This interim rule also removes the existing CFC warning statement for OTC drug products at 21 CFR 369.21 in favor of revised warning statements at new § 201.320 (a) and (c). This interim rule also removes the existing warning statement at 21 CFR 801.425 for nonrestricted devices in favor of a revised warning statement at new § 801.63 (21 CFR 801.63). Under new §§ 201.320 and 801.63, an OTC drug or device product that contains or is manufactured with CFC's or other class I substances may use the EPA warning statement or, as an alternative, state:

Note: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or other class I substance, if applicable]:

Warning: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

CONSULT WITH YOUR PHYSICIAN OR HEALTH PROFESSIONAL IF YOU HAVE ANY QUESTION ABOUT THE USE OF THIS PRODUCT.

For OTC devices, the sentence of the label shall state:

CONSULT WITH YOUR PHYSICIAN, HEALTH PROFESSIONAL, OR SUPPLIER IF YOU HAVE ANY QUESTION ABOUT THE USE OF THIS PRODUCT.

The warning statement shall appear on the product, its immediate container, its packaging, or other labeling on or within the package from which the drug is dispensed, and must also be prominent and conspicuous so as to render it likely to be read and understood by consumers under normal conditions of purchase. This statement also must be consistent with EPA's regulations at 40 CFR part 82.

The agency believes that these warning statements for OTC drug and device products, like those for prescription human medical products, enable patients, physicians, and other health professionals to appreciate environmental concerns and will also avoid unduly alarming patients.

C. Foods, Cosmetics, and Animal Foods

As noted above, no essential uses of CFC's for foods, cosmetics, or animal foods have been identified. Any uses of CFC's or of other class I substances deemed to be appropriate in the manufacture of foods, cosmetics, and animal foods, or the indirect use of such substances as additives in the manufacture of packaging materials intended to be used for foods and animal foods, will subject the foods, cosmetics, and food-packaging materials to the labeling requirements established by EPA in 40 CFR part 82. Such EPA warning statement, as cited above in the discussion on prescription and OTC medical products, must be prominent and conspicuous so as to render it easily read and understood by consumers under ordinary conditions of purchase.

Because the EPA warning statement is applicable to all products ''manufactured with'' or ''that contain CFC's or other class I substances,'' the current exemption for CFC's used as a stabilizer in food toppings and spreads is no longer appropriate and such foods must comply with the applicable labeling requirements set forth in 40 CFR part 82. Thus, FDA is removing the specific requirement for the CFC warning statement for foods, cosmetics, and animal foods in §§ 101.17(c), 740.11(c), and 501.17 and the exemption for toppings and spreads in § 101.17(c)(3). In addition, FDA is revising these sections to reference the EPA labeling requirements designated for CFC's and other class I substances in 40 CFR part 82.

III. Comments

In the Federal Register of June 29, 1993 (58 FR 34812), FDA published a notice setting out alternative labeling warnings, designed not to cause undue patient alarm, that comply with the EPA regulation, and that are acceptable to FDA. As part of the notice, FDA requested comments about the labeling warning statements, which were nearly identical to the warnings contained in this interim rule. These comments are summarized and addressed below.

1. One comment suggested that use of the FDA alternative warnings be made mandatory. The comment stated that if manufacturers did not opt for the FDA alternative warning, and used the EPA warning instead, this could cause undue concern and result in patients stopping medication.

FDA believes that manufacturers should have the option of using the warning statement that best meets their particular needs. FDA does not believe that a manufacturer will use the EPA warning if there is any real likelihood that the warning's use will cause its customers to cease using the manufacturer's product.

2. Two comments said that, due to the small size of some containers for products with CFC's, any labeling rule should allow for alternative placement of the warning on outer packaging or other labeling.

FDA considered these concerns during the drafting of this interim rule, and the interim rule does allow such alternative placement.

3. One comment suggested that the phrase in the patient warning on prescription drug labeling ''[i]f you have any questions about alternatives please consult with your physician'' was too succinct and that the warning should indicate that alternative delivery systems for the drug product may be available and that an alternative therapy may not be necessary.

FDA believes that patients will understand that the alternatives available may include alternative delivery systems for the same drug substance and that any need for additional clarity is outweighed by the necessity of keeping this general warning concise.

4. Another comment suggested that the patient warning statement was not sufficiently inclusive in directing patients to contact their physician or pharmacist. The comment suggested that labeling refer to ''physician or health professional'' so as to refer to other health care professionals, such as physician's assistants or nurses, who can and do provide patients with information on drug products and medical devices.

FDA agrees with this comment in regard to OTC products. Health care professionals, other than physicians and pharmacists, are competent to advise patients on OTC therapies. However, in regard to prescription products, FDA believes that, in such a brief warning, the modification may cause confusion and may cause consumers to direct questions to health care professionals other than the prescribing physician (or other authorized prescribing practitioner) and dispensing pharmacist. In such event, the patient could receive inadequate or inappropriate advice.

5. Several comments stated that the physician package insert does not alert

the physician to the fact that patients have been instructed to consult with their physician about possible alternatives. Two comments suggested that the warning on the physician package insert contain the following additional sentence: ''The patient has been instructed to consult with you if they have questions about alternatives.''

FDA agrees with the comment and has reworded the warning in the physician package insert with language to that effect.

Another comment suggested that the proposed OTC drug product warning was unduly worrisome to consumers and that a warning similar to the alternative warning contained in patient labeling for prescription products be allowed for OTC drug products.

EPA's regulations allow an exception to the general rule of requiring the EPA warning only on patient labeling for prescription products when the EPA warning is contained in the physician labeling for the product. No similar exception is provided for OTC drug products; therefore, the warning suggested in the comment would not be in compliance with EPA regulations.

IV. Implementation Scheme

FDA advises applicants who have an approved new drug application (NDA) and whose products contain or are manufactured with CFC's or other ozone-depleting substances to use the existing procedures in 21 CFR 314.70(c) (supplements for changes that may be made before FDA approval) to notify the agency of any labeling changes to add a CFC warning statement. Applicants who have an approved abbreviated new drug application (ANDA) should follow the same procedures (see 21 CFR 314.97).

Applicants who have submitted either an NDA or ANDA but have not received approval should, if necessary, amend their applications to notify FDA about the warning statement(s) they intend to use. Applicants should submit such amendments in accordance with 21 CFR 314.60 or 314.96, whichever is appropriate.

Applicants who hold an approved product license application (PLA) and whose products contain or are manufactured with CFC's or other ozone-depleting substances are to follow the guidance offered in this interim rule. Revision of labeling to accommodate this warning statement may be implemented without preclearance from the Center for Biologics Evaluation and Research (CBER) and submitted to the file as final printed labeling provided that the placement of such information does not interfere with or render less prominent any information required by biologics labeling regulations (21 CFR 610.60 through 610.65)).

Applicants who have submitted a PLA but have not yet received approval should, if necessary, amend their applications to notify CBER about inclusion of the required warning statement(s) they intend to use. Such amendments should be submitted under the applicable reference number.

Applicants who have submitted premarket approval applications (PMA's) for medical devices but have not received approval should, if necessary, amend their applications to notify FDA about the warning statement(s) they intend to use. Applicants should submit such amendments in accordance with 21 CFR 814.37. With respect to approved PMA's, applicants should use the procedures in 21 CFR 814.39 to notify the agency of any labeling changes to add a CFC warning. Applicants who have received premarket clearance pursuant to 21 U.S.C. 360(k) (''510(k) clearance'') do not need to file a new 510(k) submission requesting new clearance if this rule only results in the addition of the warning statement to the labeling.

FDA advises applicants who have an approved new animal drug application (NADA) and whose products contain or are manufactured with CFC's or other ozone-depleting products to use the existing procedures as identified in 21 CFR 514.8(e) (supplements for changes which may be made before FDA approval) to notify the agency of any labeling changes made to add the CFC warning statement. FDA advises applicants who have submitted an NADA but have not received approval should, if necessary, amend their applications to reflect the required label warning. No notification to the agency is necessary for foods, cosmetics, or animal foods.

Manufacturers who amended their labeling to conform with the June 29, 1993, notice and who have an approved marketing application for their product should submit a supplemental application to bring their labeling into compliance with this interim rule. Such manufacturers may continue to use their current stocks of labeling that comply with the June 29, 1993, notice until those stocks are exhausted.

V. Effective Date and Opportunity for Public Comment

For the reasons described in this section, FDA is issuing these requirements as an interim rule with an opportunity for public comment. In view of the May 15, 1993, statutory warning label requirement, the agency is issuing these requirements at this time, but FDA will consider modifications to the regulations based on issues raised during the comment period and experience gained under the interim rule.

The Administrative Procedure Act provides an exception to notice and comment rulemaking when an agency, for good cause, finds that the notice and comment procedures are impracticable, unnecessary, or contrary to the public interest (see 5 U.S.C. 553(b)(B)). For this interim rule, FDA finds that notice and comment procedures would be impracticable for a CFC warning statement requirement because the Clean Air Act requires such warning statements to be placed on products containing or manufactured with CFC's or other ozone-depleting substances by May 15, 1993.

FDA also finds that notice and comment rulemaking to be unnecessary and contrary to the public interest. The interim rule permits parties to use the EPA warning statement or an alternative FDA statement. FDA has no authority to change or modify the warning statements established in EPA's regulations, and, in this interim rule, offers, but does not require, the use of an alternative statement. Consequently, because one warning statement is established by another agency and because the alternative warning statement is optional, FDA believes that notice and comment procedures are unnecessary. Furthermore, FDA believes that, without the availability of the alternative warning statement, patients who are concerned about a medical product's impact on the environment and public health might inappropriately refrain from taking their medication. This interim rule provides an alternative warning statement that encourages patients to continue taking their medication and to consult their physicians, pharmacists, other health professionals, or, in the case of devices, their suppliers, concerning the product's effect on the environment or public health. It would, therefore, be contrary to the public interest to delay the implementation of this rule pending notice and comment rulemaking.

FDA believes, however, that it should invite and consider public comment on its practices and procedures for these CFC warning statements. Interested persons may, on or before August 1, 1996, submit to the Dockets Management Branch (address above) comments regarding this interim rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VI. Analysis of Impacts

FDA has examined the impacts of the interim rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this interim rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the interim rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The regulatory impact analysis (RIA) (January 1993) that accompanied EPA's rule that implemented section 611 of the Clean Air Act specifically accounted for cost increases for ''medical aerosols, including metered-dose inhalation devices, contraceptive foams, topical antibiotics, and local anesthetics'' (page 15 of the RIA). A copy of this RIA is available for examination under Public Docket No. A–91–60 at the U.S. Environmental Protection Agency, rm. M–1500, Waterside Mall (Ground Floor), 401 M St. SW., Washington, DC 20460. Other FDA-regulated products are accounted for under separate industry subgroupings. The compliance costs for these labeling changes have thus been accounted for, and this interim rule adds no additional burden or cost. Thus, the agency certifies that the interim rule does not constitute a major rule as defined in Executive Order 12866. The agency further certifies that the interim rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

21 CFR Part 501

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 740

Cosmetics, Labeling.

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Fair Packaging and Labeling Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101, 201, 369, 501, 740, and 801 are amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.17 is amended by revising paragraph (c) to read as follows:

§ 101.17 Food labeling warning and notice statements.

* * * * *

(c) *Food containing or manufactured with a chlorofluorocarbon or other ozone-depleting substance.* Labeling requirements for foods that contain or are manufactured with a chlorofluorocarbon or other ozone-depleting substance designated by the Environmental Protection Agency (EPA) are set forth in 40 CFR part 82.

* * * * *

PART 201—LABELING

3. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 510, 512, 530–542, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360, 360b, 360gg–360ss, 371, 374, 379e); secs. 215, 301, 351, 361 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 264).

4. New § 201.320 is added to subpart G to read as follows:

§ 201.320 Warning statements for drug products containing or manufactured with chlorofluorocarbons or other ozone-depleting substances.

(a)(1) All drug products containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other class I substance designated by the Environmental Protection Agency (EPA) shall, except as provided in paragraph (b) or (c) of this section, bear the following warning statement:

Warning: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and the environment by destroying ozone in the upper atmosphere.

(2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase.

(b)(1) For prescription drug products for human use, the following alternative warning statement may be used:

Note: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or name of other class I substance, if applicable]:

This product contains [or is manufactured with, if applicable] [*insert name of substance*], a substance which harms the environment by destroying ozone in the upper atmosphere.

Your physician has determined that this product is likely to help your personal health. USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY YOUR PHYSICIAN. If you have any questions about alternatives, consult with your physician.

(2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase.

(3) If the warning statement in paragraph (b)(1) of this section is used, the following warning statement must

be placed on the package labeling intended to be read by the physician (physician package insert) after the ''How supplied'' section, which describes special handling and storage conditions on the physician labeling:

Note: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or name of other class I substance, if applicable]:

Warning: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and the environment by destroying ozone in the upper atmosphere.

A notice similar to the above WARNING has been placed in the information for the patient [or patient information leaflet, if applicable] of this product under the Environmental Protection Agency's (EPA's) regulations. The patient's warning states that the patient should consult his or her physician if there are questions about alternatives.

(c)(1) For over-the-counter drug products for human use, the following alternative warning statement may be used:

Note: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or other class I substance, if applicable]:

Warning: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

CONSULT WITH YOUR PHYSICIAN OR HEALTH PROFESSIONAL IF YOU HAVE ANY QUESTION ABOUT THE USE OF THIS PRODUCT.

(2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase.

(d) This section does not replace or relieve a person from any requirements imposed under 40 CFR part 82.

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

5. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371).

§ 369.21 [Amended]

6. Section 369.21 *Drugs; warning and caution statements required by regulations* is amended in paragraph (d) in the warning section for ''DRUGS IN DISPENSERS PRESSURIZED BY GASEOUS PROPELLANTS * * *'' by removing the five undesignated paragraphs after the introductory text of paragraph (d).

PART 501—ANIMAL FOOD LABELING

7. The authority citation for 21 CFR part 501 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

8. Section 501.17 is amended by revising paragraph (c) to read as follows:

§ 501.17 Animal food labeling warning statements.

* * * * *

(c) *Animal food containing or manufactured with a chlorofluorocarbon or other ozone-depleting substance.* Labeling requirements for animal foods that contain or are manufactured with a chlorofluorocarbon or other ozone-depleting substance designated by the Environmental Protection Agency (EPA) are set forth in 40 CFR part 82.

PART 740—COSMETIC PRODUCT WARNING STATEMENTS

9. The authority citation for 21 CFR part 740 continues to read as follows:

Authority: Secs. 201, 301, 502, 505, 601, 602, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374).

10. Section 740.11 is amended by revising paragraph (c) to read as follows:

§ 740.11 Cosmetics in self-pressurized containers.

* * * * *

(c) Labeling requirements for cosmetics packaged in a self-pressurized container containing or manufactured with a chlorofluorocarbon propellant or other ozone-depleting substance designated by the Environmental Protection Agency (EPA) are set forth in 40 CFR part 82.

PART 801—LABELING

11. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

12. New § 801.63 is added to subpart C to read as follows:

§ 801.63 Medical devices; warning statements for devices containing or manufactured with chlorofluorocarbons and other class I ozone-depleting substances.

(a) All over-the-counter devices containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other class I substance designated by the Environmental Protection Agency (EPA) shall carry one of the following warnings:

(1) The EPA warning statement:

Warning: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

(2) The alternative statement:

Note: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or other class I substance, if applicable]:

Warning: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

CONSULT WITH YOUR PHYSICIAN, HEALTH PROFESSIONAL, OR SUPPLIER IF YOU HAVE ANY QUESTION ABOUT THE USE OF THIS PRODUCT.

(b) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase. This provision does not replace or relieve a person from any requirements imposed under 40 CFR part 82.

§ 801.425 [Removed]

13. Section 801.425 *Nonrestricted devices in self-pressurized containers with chlorofluorocarbon propellants* is removed from subpart H.

14. New § 801.433 is added to subpart H to read as follows:

§ 801.433 Warning statements for prescription and restricted device products containing or manufactured with chlorofluorocarbons or other ozone-depleting substances.

(a)(1) All prescription and restricted device products containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other class I substance designated by the Environmental

Protection Agency (EPA) shall, except as provided in paragraph (b) of this section, bear the following warning statement:

Warning: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

(2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase.

(b)(1) For prescription and restricted device products, the following alternative warning statement may be used:

Note: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or name of other class I substance, if applicable]:

This product contains [or is manufactured with, if applicable] [*insert name of substance*], a substance which harms the environment by destroying ozone in the upper atmosphere.

Your physician has determined that this product is likely to help your personal health. USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY YOUR PHYSICIAN. If you have any questions about alternatives, consult with your physician.

(2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase.

(3) If the warning statement in paragraph (b)(1) of this section is used, the following warning statement must be placed on the package labeling intended to be read by the physician (physician package insert) after the ''How supplied'' section, which describes special handling and storage conditions on the physician labeling:

Note: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or name of other class I substance, if applicable]:

Warning: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

A notice similar to the above WARNING has been placed in the information for the patient [or patient information leaflet, if applicable] of this product under Environmental Protection Agency (EPA) regulations. The patient's warning states that the patient should consult his or her physician if there are questions about alternatives.

(c) This section does not replace or relieve a person from any requirements imposed under 40 CFR part 82.

Dated: April 16, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–10961 Filed 5–2–96; 8:45 am]

BILLING CODE 4160–01–P