products. A statutory phaseout of CFC propellants used in these MDI aerosol products exists, although an exemption for MDI's for the treatment of asthma and COPD exists through 1997. Based on this phaseout, manufacturers may eventually decide or need to reformulate their existing MDI aerosol products with non-CFC-containing propellant systems. The agency considers it essential that any such reformulated products be evaluated and approved by the agency before they are marketed.

Consequently, the agency is proposing to amend § 341.76(d)(2) of the final monograph for OTC bronchodilator drug products to remove  $\S341.76(d)(2)(i)(a)$ and (d)(2)(i)(b). The agency proposes amending § 310.545(a)(6) for bronchodilator drug products by adding new paragraph (C) and listing thereunder "any ingredient(s) in a pressurized metered-dose aerosol container." The proposal would also remove § 341.76(e) from the final monograph because that information now appears in § 330.1(i) (21 CFR 330.1(i)) as part of the general labeling policy for OTC drug products.

FDA has examined the impacts of the proposed 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and, thus, 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. All currently marketed MDI aerosol drug products are currently the subject of an approved application. This proposed amendment of the monograph will not affect the status of any currently marketed product. As is currently the case for marketed MDI aerosol products, an approved application will be required for any product that is reformulated to contain a non-CFC propellant. Accordingly, the agency certifies that the proposed 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.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC bronchodilator MDI aerosol drug products that contain epinephrine, epinephrine bitartrate, and racepinephrine hydrochloride. Comments regarding the impact of this rulemaking on these drug products should be accompanied by appropriate documentation. A period of 75 days from the date of publication of this proposed rulemaking in the Federal **Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined that under 21 CFR 25.24(c)(6) 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.

Interested persons may, on or before May 23, 1995, submit written comments or objections to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before May 23, 1995. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting memorandum or brief. Comments and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

# List of Subjects

#### 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

### 21 CFR Part 341

Labeling, Over-the-counter drugs. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 310 and 341 be amended as follows:

# PART 310-NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

2. Section 310.545 is amended by adding new paragraphs (a)(6)(iv) and (d)(26) and by revising paragraph (d) introductory text to read as follows:

#### § 310.545 Drug products containing certain active ingredients offered over-thecounter (OTC) for certain uses.

(a) \* \* \*

(6) \* \* \*

(iv) Bronchodilator drug products.

(A)—(B) [Reserved]

(C) Approved as of April 10, 1995. Any ingredient(s) in a pressurized metered-dose inhaler container.

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(26) of this section.

(26) April 10, 1995, for products subject to paragraph (a)(6)(iv)(C) of this section.

## PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR part 341 continues to read as follows:

**Authority:** Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

# §341.76 [Amended]

4. Section 341.76 is amended by removing paragraphs (d)(2)(i) and (e); by redesignating paragraph (d)(2)(i) as (d)(2), and revising the paragraph heading to read as follows:

# § 341.76 Labeling of bronchodilator drug products.

- \* \* \*
- (d)\* \* \*

(2) For products containing epinephrine, epinephrine bitartrate, and racepinephrine hydrochloride identified in § 341.16(d), (e), and (g) for use in a hand-held rubber bulb nebulizer. \* \* \* \* \* \* \* \* \*

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