

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 2006N-0416]

RIN 0910-AF93

Use of Ozone-Depleting Substances; Removal of Essential Use Designations; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing this companion proposed rule to the direct final rule, published elsewhere in this issue of the **Federal Register**, that is intended to amend our regulation on the use of ozone-depleting substances (ODSs) in pressurized containers to remove the essential use designations for beclomethasone, dexamethasone, fluticasone, bitolterol, salmeterol, ergotamine tartrate, and ipratropium bromide used in oral pressurized metered-dose inhalers (MDIs). Under the Clean Air Act, FDA, in consultation with the Environmental Protection Agency (EPA), is required to determine whether an FDA-regulated product that releases an ODS is essential. None of these products is currently being marketed, which provides grounds for removing their essential use designation.

DATES: Submit written or electronic comments by [*insert date 75 days after date of publication in the Federal Register*].

ADDRESSES: You may submit comments, identified by Docket No. 2006N-0416 and RIN Number 0910-AF93, by any of the following methods:

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2006N-0416

NPR 1

Display No.	12-6-06
Publication	12-7-06
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Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and

insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen or Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

As described more fully in the related direct final rule, the Clean Air Act prohibits most uses of chlorofluorocarbons (CFCs) (a class of ODSs). Medical products which FDA, in consultation with EPA, determines to be essential are exempt from the general ban. In 1978, we published a rule listing several essential uses of CFCs and providing criteria for adding new essential uses (43 FR 11301 at 11316, March 17, 1978). The rule was codified as § 2.125 (21 CFR 2.125) and was subsequently amended various times to add or remove essential uses. In 2002, we amended § 2.125 to provide, among other things, criteria for the removal of additional essential use designations in the future. The rule provides that if any product that releases an ODS is no longer being marketed, the product may have its essential use designation revoked through notice-and-comment rulemaking.

We are proposing to amend our regulations to remove oral pressurized metered-dose inhalers releasing beclomethasone, dexamethasone, fluticasone, bitolterol, salmeterol, ergotamine tartrate, and ipratropium bromide from the list of essential uses of ODSs found at § 2.125(e) (21 CFR 2.125(e)). None of these products is currently being marketed in MDIs that release ODSs, which, under § 2.125(g)(1) (21 CFR 2.125(g)(1)), is grounds for removing the essential

use status. Because these products are no longer being marketed, this action will not result in any drugs being made unavailable to patients.

II. Additional Information

This proposed rule is a companion to the direct final rule published in the final rules section in this issue of the **Federal Register**. This companion proposed rule and the direct final rule are identical in substance. This companion proposed rule will provide the procedural framework to proceed with standard notice-and-comment rulemaking in the event the direct final rule receives significant adverse comment and is withdrawn. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule and vice-versa.

A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to the companion proposed rule. Instead, we will publish a confirmation notice within 30 days after the comment period ends, and we intend the direct final rule to become effective 30 days after publication of the confirmation notice, except for § 2.125(e)(4)(v) (21 CFR 2.125(e)(4)(v)), which we intend to become effective August 1, 2007.

If we receive significant adverse comments, we will withdraw the direct final rule. We will proceed to respond to all the comments received regarding

the direct final rule, treating those comments as comments to this proposed rule. The agency will address the comments in the subsequent final rule. We will not provide additional opportunity for comment. If we receive a significant adverse comment which applies to part of the rule and that part may be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of significant adverse comment.

For additional background information, see the corresponding direct final rule published in the final rules section in this issue of the **Federal Register**. All persons who may wish to comment should review the complete rationale for this amendment set out in the preamble of the direct final rule.

III. Environmental Impact

We have carefully considered, under 21 CFR part 25, the potential environmental effects of this action. We have concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. Our finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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 not a significant regulatory action as defined by 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. Because we are proposing to remove the essential use designations for certain drug products that are either no longer being marketed or are no longer being marketed in a formulation releasing ODSs, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$118 million, using the most current (2004) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

V. The Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the

relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, we do not plan to prepare a federalism summary impact statement for this rulemaking procedure. We invite comments on the federalism implications of this proposed rule.

VII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. This comment period runs concurrently with the comment period for the direct final rule; any comments received will be considered as comments regarding the direct final rule. Submit a single copy of electronic comments or two copies of any mailed comments, 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 2

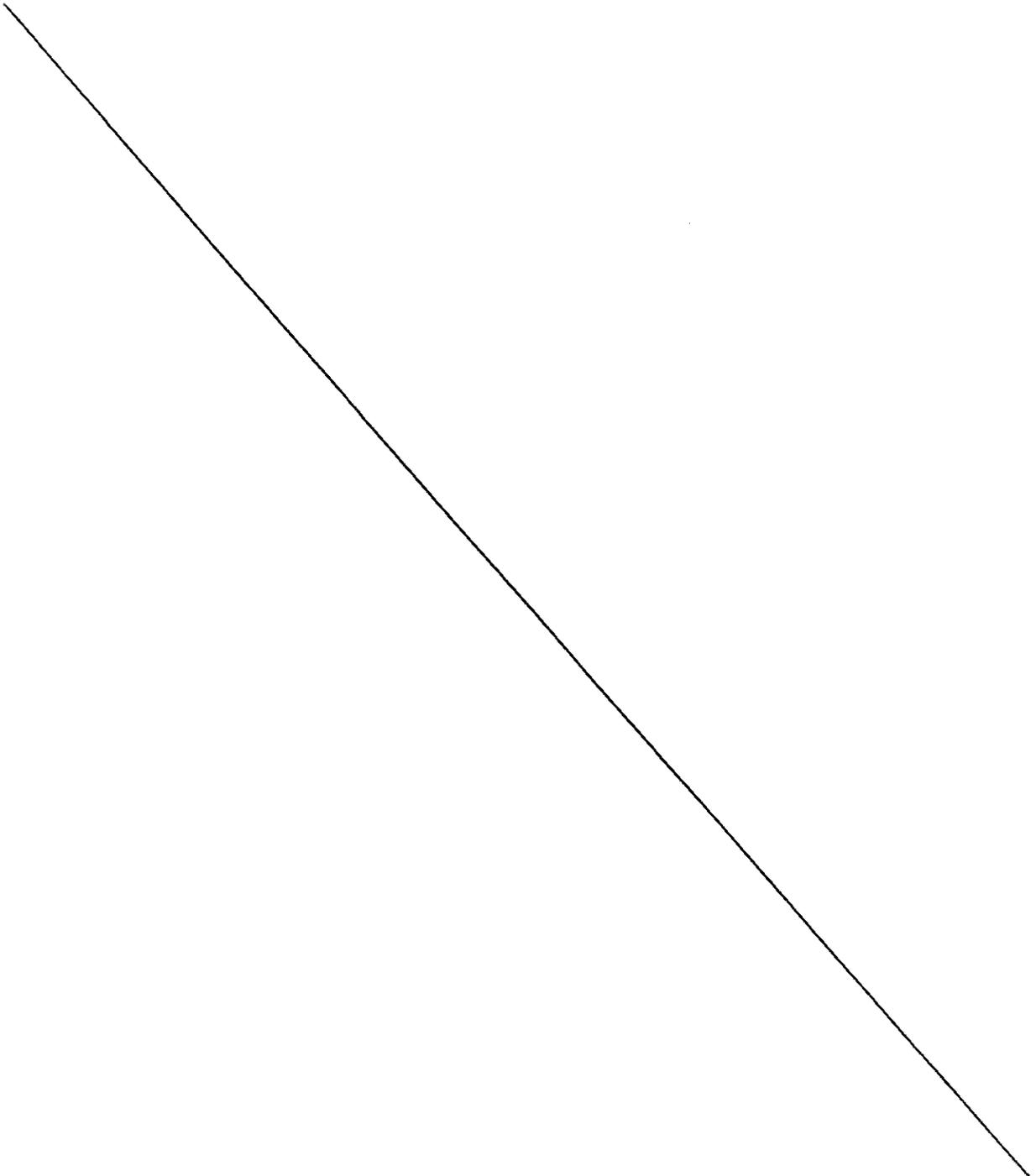
Administrative practice and procedure, Cosmetics, Drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Clean Air Act, and under authority delegated to the Commissioner of Food and Drugs, after consultation with the Administrator of the Environmental Protection Agency, it is proposed that 21 CFR part 2 be amended as follows:

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

1. The authority citation for 21 CFR part 2 continues to read as follows:

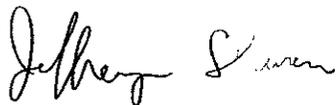
Authority: 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348,
351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*



§2.125 [Amended]

2. Section 2.125 is amended by removing and reserving paragraphs (e)(1)(i), (e)(1)(ii), (e)(1)(iv), (e)(2)(ii), (e)(4)(i), (e)(4)(ii), and (e)(4)(v).

Dated: 10/13/06
October 13, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

BILLING CODE 4160-01-S

