4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1995-N-0031] (formerly Docket No. 1995N-0205)

Compliance Guidance for Small Business Entities on Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance guidance for small business entities entitled "Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Small Entity Compliance Guide." This guidance is intended to help small businesses understand and comply with the requirements of the final rule that provides new labeling applicable to all over-the-counter (OTC) bronchodilator drug products marketed without an approved application. The guidance describes the bronchodilator labeling requirements in plain language and provides answers to common questions on how to comply with the rule. This guidance was prepared in accordance with the Small Business Regulatory Fairness Act.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one

self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Elaine Abraham,

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301-796-2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a compliance guidance for small business entities entitled "Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Small Entity Compliance Guide." This small entity compliance guide applies to OTC bronchodilator drug products used to treat asthma that are marketed without an approved application (i.e., under the OTC bronchodilator monograph) (21 CFR part 341). OTC bronchodilators are those that contain any of the ephedrine ingredients (i.e., ephedrine, ephedrine hydrochloride, ephedrine sulfate, and

racephedrine hydrochloride) or epinephrine ingredients (i.e., epinephrine, epinephrine bitartrate, and racepinephrine hydrochloride) listed under 21 CFR 341.16.

This guidance summarizes the July 26, 2011, final rule (76 FR 44475) regarding OTC bronchodilator drug products, which makes the following changes to the OTC regulations:

- Sets forth a new use statement, warnings (including an Asthma Alert warning), and directions that are required in the labeling of OTC bronchodilator drug products under 21 CFR 341.76.
- Revises labeling requirements for OTC bronchodilator drug products to ensure consistency with the standardized Drug Facts content and formatting requirements set forth in 21 CFR 201.66.

Manufacturers must be in compliance with the rule beginning on January 23, 2012.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on labeling for OTC bronchodilator drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: November 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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