4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1086]

Compliance Guidance for Small Business Entities on Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Notice of 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 and Effectiveness Testing: Sunscreen 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 addressing labeling and effectiveness testing requirements for over-the counter (OTC) sunscreen drug products. The guidance describes the requirements of the final rule 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 Enforcement 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:

Reynold Tan,

Center for Drug Evaluation and Research,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 22, rm. 5493,

Silver Spring, MD 20993-0002,

301-796-1009.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a compliance guidance for small business entities entitled "Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-the-Counter Human Use; Small Entity Compliance Guide." This guidance summarizes the June 17, 2011, final rule (76 FR 35620) regarding labeling and testing requirements for OTC sunscreen drug products. Under the 2011 sunscreen final rule, required and permitted labeling is based upon the results of effectiveness testing. The effectiveness testing consists of a sun protection factor (SPF) Test and a Broad Spectrum (ultraviolet A (UVA) and ultraviolet B (UVB) protection) Test. In addition, a test demonstrating water resistance that accompanies the SPF Test to ensure retention of SPF protection while swimming or sweating is described. The 2011 sunscreen final rule makes the following changes to OTC sunscreen drug product regulations:

- Requires that OTC sunscreen drug products follow Drug Facts labeling content and format requirements in § 201.66 (21 CFR 201.66).
- Establishes new labeling requirements for marketed OTC sunscreen drug products set forth in § 201.327 (21 CFR 201.327).
- Revises SPF, broad spectrum, and water-resistant testing requirements and the indications and claims allowed based upon the results of these tests in § 201.327(i) and (j).

FDA is issuing this compliance guidance for small business entities as a level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the testing requirements for OTC sunscreen drug products and revision of labeling requirements for OTC sunscreen 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in § 201.327 have been approved under OMB control number 0910-0717.

III. 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.

IV. 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 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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