

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0387]

DPM

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Certifier Spice

**Draft Guidance for Industry on Labeling OTC Skin Protectant Drug Products;  
Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Labeling OTC Skin Protectant Drug Products." This guidance provides recommendations on how to label over-the-counter (OTC) skin protectant drug products. An OTC skin protectant active ingredient can be combined with another OTC skin protectant active ingredient or OTC external analgesic, first aid antiseptic, or sunscreen active ingredients. Each of these combinations has specific labeling requirements, and therefore labeling of OTC skin protectant drug products is complex. This guidance is designed to clarify the permitted combinations of active ingredients along with the corresponding required labeling.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research,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. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Michael L. Koenig, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5424, Silver Spring, MD 20993-0002, 301-796-2090.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Labeling OTC Skin Protectant Drug Products.” In the **Federal Register** of June 4, 2003 (68 FR 33362), FDA published a final rule establishing conditions under which OTC skin protectant drug products are generally recognized as safe and effective and not misbranded. In developing this final rule, FDA acknowledged the complex task that manufacturers of these products would face in meeting all the pertinent labeling requirements. This draft guidance provides recommendations on how to meet current labeling requirements according to OTC skin protectant active ingredient.

Because OTC skin protectant active ingredients can be combined with active ingredients from other OTC drug product categories, this draft guidance is based upon the following rulemakings: (1) Final rule for OTC skin protectant

drug products (68 FR 33362, June 4, 2003); (2) final rule for format and content of labeling of OTC drugs (64 FR 13254, March 17, 1999); (3) proposed rule for OTC sunscreen drug products (72 FR 49070, August 27, 2007); (4) proposed rule for OTC external analgesic drug products (48 FR 5852, February 8, 1983); and (5) proposed rule for OTC first aid antiseptic drug products (56 FR 33644, July 22, 1991).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on labeling OTC skin protectant 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**

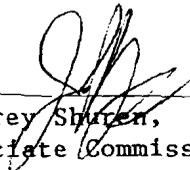
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket numbers 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.regulations.gov>.

Dated: 7/28/08  
July 28, 2008.

  
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Jeffrey Shuren,  
Associate Commissioner for Policy and Planning.

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