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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0277]

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Certifier J. [Signature]

Draft Guidance for Industry on Time and Extent Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Time and Extent Applications." This guidance is being written to assist those persons interested in adding a new condition to the over-the-counter (OTC) drug monograph system. A time and extent application (TEA) can be submitted for FDA to determine whether a condition is eligible to be considered for inclusion in an OTC drug monograph. This guidance is designed to clarify issues concerning the TEA in an effort to facilitate the application process.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Matthew R. Holman, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Time and Extent Applications.” The OTC drug monograph system was established to evaluate the safety and effectiveness of all OTC drug products for the following reasons: (1) Marketed in the United States before May 11, 1972, that were not covered by new drug applications (NDAs), and (2) covered by “safety” NDAs that were marketed in the United States before enactment of the 1962 drug amendments to the Federal Food, Drug, and Cosmetic Act (the act). In 1972, FDA began its OTC drug review of the following procedures: (1) To evaluate OTC drugs by categories or classes (e.g., antacids, skin protectants), rather than on a product-by-product basis, and (2) to develop “conditions” under which classes of OTC drugs are generally recognized as safe and effective (GRAS/E) and not misbranded.

FDA publishes these conditions in the **Federal Register** in the form of OTC drug monographs, which consist primarily of active ingredients, labeling, and other general requirements. Final monographs for OTC drugs that are GRAS/E and not misbranded are codified in part 330 (21 CFR part 330). Manufacturers seeking to market an OTC drug covered by an OTC drug monograph need not obtain FDA approval before marketing.

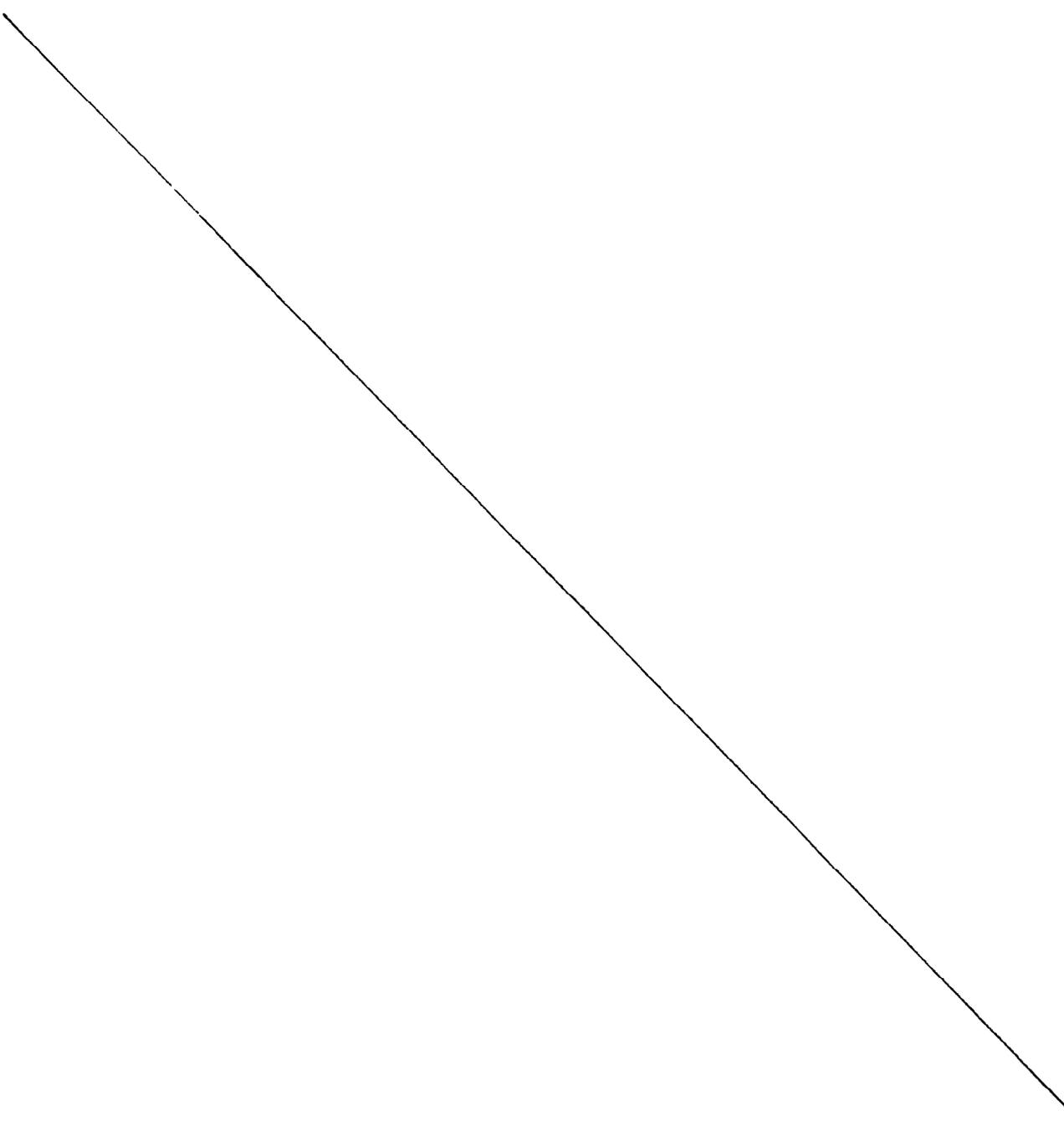
Previously, interested persons had to prepare and submit an NDA if they wanted to introduce into the United States an OTC drug condition that had been marketed solely in a foreign country. Companies also had to submit an NDA if their OTC drug products were initially marketed in the United States after the OTC drug review began in 1972. In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule that amended the OTC drug review procedures in part 330 and included additional criteria and procedures for classifying OTC drugs as GRAS/E and not misbranded. The final rule provided procedures for conditions that previously required an NDA for those conditions to become eligible for inclusion in the OTC drug monograph system. This final rule stated that an applicant must first submit a TEA to show marketing “to a material extent” and “for a material time.” Once FDA has determined eligibility, safety and effectiveness data would be submitted and evaluated. This two-step process allows applicants to demonstrate that eligibility criteria are met before expending resources to prepare safety and effectiveness data.

This draft guidance is being issued consistent with FDA’s good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on time and extent applications. 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 on the draft guidance. Two copies

of mailed comments are to be submitted, 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



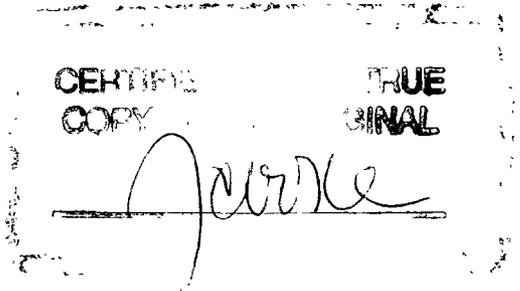
III. Electronic Access

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

Dated: January 29, 2004
January 29, 2004.

William K. Hubbard

William K. Hubbard,
Associate Commissioner for Policy and Planning.



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