Dated: September 26, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0438 (Formerly 2004D–0027)]

Guidance for Industry on Time and Extent Applications for Nonprescription Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Time and Extent Applications for Nonprescription Drug Products.” This guidance describes a two-step process on how to request that a new condition be added to the over-the-counter (OTC) drug monograph system. The process includes submitting a time and extent application (TEA) to determine whether a condition is eligible for inclusion in the OTC drug monograph system and, if the condition is found to be eligible, submitting safety and effectiveness data. This guidance is designed to clarify the TEA process and what happens after a TEA is submitted. This guidance finalizes the draft guidance for industry entitled “Time and Extent Applications” published in the Federal Register on February 10, 2004 (69 FR 6309).

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. 22, rm. 5488, Silver Spring, MD 20993–0002, 301–796–2090. Written requests for single copies of this guidance, written comments on the draft guidance, or written questions about how to prepare an application for review by the Office of Management and Budget (OMB) on the Paperwork

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Time and Extent Applications for Nonprescription Drug Products.” This guidance provides information about how to request that a new condition be added to the OTC drug monograph system. The OTC drug monograph system was established to evaluate the safety and effectiveness of all OTC drug products marketed in the United States before May 11, 1972, that were not marketed under approved new drug applications (NDAs) and all OTC drug products 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 FD&C Act). In 1972, FDA began its OTC drug review to evaluate eligible OTC drug products by categories or classes (e.g., antacids, skin protectants), rather than on a product-by-product basis, and to develop “conditions” under which classes of OTC drug products are generally recognized as safe and effective (GRASE) and not misbranded. FDA publishes these conditions, including active ingredients, labeling, and other general conditions under which a class of OTC drug products is considered GRASE, in the Federal Register in the form of OTC drug monographs. Final monographs are codified in 21 CFR parts 331 through 358. Manufacturers seeking to market an OTC drug product covered by an OTC drug monograph need not obtain FDA approval before marketing if their drug product meets the conditions in part 330 (21 CFR part 330) and the applicable final monograph (§ 330.1).

Before § 330.14 went into effect in 2002, there was no formal process to add OTC drug products that had not been marketed in the United States before May 11, 1972, to the OTC drug monograph system. Interested persons were required to obtain premarketing approval under section 505 of the FD&C Act to be marketed, were eligible to be considered for inclusion in the OTC drug monograph system. Under the regulation in § 330.14, an applicant must first submit a TEA to show that the drug product is eligible for inclusion in the OTC drug monograph system by showing that the drug product has been marketed “to a material extent” and “for a material time.” If FDA determines that the condition meets the time and extent eligibility criteria, FDA publishes a notice of eligibility in the Federal Register, and the applicant and other interested parties have the opportunity to submit safety and effectiveness data to FDA for evaluation. This two-step process allows applicants to demonstrate that eligibility criteria are met before expending resources to prepare safety and effectiveness data.

In the Federal Register of February 10, 2004, FDA announced the availability of the draft guidance for industry entitled “Time and Extent Applications.” FDA received comments on the draft guidance, considered those comments, and revised the guidance as appropriate. The finalized TEA guidance announced in this document replaces the February 2004 draft guidance. This guidance is designed to clarify the TEA process. We are providing this guidance because we have received inquiries from the public regarding the TEA process.

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 TEAs. 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. 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

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

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.

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