Dated: September 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25115 Filed 9–28–11; 8:45 am]

BILLING CODE 4160–01–P

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 This guidance finalizes the draft guidance for industry entitled ''Time and Extent Applications'' published in the **Federal Register** on February 10, 2004 (69 FR 6309).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. 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: Ruth E. Scroggs, 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.

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 (21 U.S.C. 355) if they wanted to introduce into the United States an OTC drug product that had been marketed solely in a foreign country. Companies also were required to obtain premarketing approval to market OTC drug products 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 drug products as GRASE and not misbranded. The final rule provided a process for establishing that certain OTC drug products, which previously required 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

Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 330.14 have been approved under OMB control number 0910–0688. The collections of information in 21 CFR part 25 and the guidance for industry entitled ''Environmental Assessment of Human Drug and Biologics Applications,'' which are referenced in the guidance announced in this document, are approved under OMB control number 0910–0322.

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.*

Dated: September 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25118 Filed 9–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0690]

Center for Drug Evaluation and Research, Approach to Addressing Drug Shortage; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is opening a comment period for the notice of public workshop published in the **Federal Register** of July 28, 2011 (76 FR 45268). In that notice, FDA announced a public workshop regarding the approach of the Center for Drug Evaluation and Research to addressing drug shortages. FDA is opening a comment period in light of public interest in this topic and in order to gain additional insight about the causes and impact of drug shortages, and possible strategies for preventing or mitigating drug shortages.

DATES: Either electronic or written comments will be accepted after the workshop until December 23, 2011.

ADDRESSES: Submit electronic comments 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: Christine Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6202, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA held a public workshop regarding CDER's current approach to addressing drug shortages. Given the increasing number of drug shortages and the attendant safety concerns for the public's health, it is important to discuss the causes of these shortages, as well as strategies to address them. This public workshop focused on collecting information and gaining perspective from professional societies, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons. The topics discussed: How CDER becomes aware of drug shortages, Reasons behind drug shortages, Determination of medically necessary products, CGMP (current good manufacturing practice) and other compliance issues, Actions taken when a drug shortage occurs, and Outcomes of mitigated drug shortages. Additional discussions included the public health impact of drug shortages and what measures can be taken to prevent the occurrence of a drug shortage. The Agency encouraged professional societies, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

II. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov,* approximately 45 days after the public workshop. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

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.

Dated: September 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25116 Filed 9–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Food Defense Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Regional Office (SWRO), in cosponsorship with Oklahoma State University, Robert M. Kerr Food & Agricultural Products Center (FAPC), is announcing a public workshop entitled ''Food Defense Workshop.'' This public workshop is intended to provide information about food defense as it relates to food facilities such as farms, manufacturers, processors, distributors, retailers, and restaurants.

Date and Time: This public workshop will be held on November 2, 2011, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Robert M. Kerr Food & Agricultural Products Center, Oklahoma State University, 148 FAPC, Stillwater, OK 74078–6055.

Contact: David Arvelo, Office of Regulatory Affairs, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214–253–