TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
203.31(d)(1) and (d)(2)	2,208	1	2,208	40	88,320
203.31(d)(4)	442	1	442	24	10,608
203.31(e)	2,208	1	2,208	1	2,208
203.34	90	1	90	40	3,600
203.37(a)	50	4	200	6	1,200
203.37(b)	50	40	2000	6	1,200
203.39(d)	65	1	65	1	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8	25,768
203.39(g)	3,221	1	3,221	8	25,768
203.50(a)	125	100	12,500	.17	2,125
203.50(b)	125	100	12,500	.50	6,250
203.50(d)	691	1	691	2	1,382
Total					332,769

[1] There are no operating and maintenance costs or capital costs associated with this collection of information.

Dated: September 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25117 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–D–0023]

Guidance for Industry on Target Animal Safety and Effectiveness Protocol Development and Submission; 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 (#215) entitled ''Target Animal Safety and Effectiveness Protocol Development and Submission.'' The purpose of this document is to provide sponsors guidance in preparation of study protocols for review by the Center for Veterinary Medicine, Office of New Animal Drug Evaluation. The recommendations included in this guidance are intended to reduce the time to protocol concurrence.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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: Angela Clarke, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8318; *e-mail: angela.clarke@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 3, 2011 (76 FR 6143), FDA published the notice of availability for a draft guidance entitled ''Target Animal Safety and Effectiveness Protocol Development and Submission,'' giving interested persons until April 19, 2011, to comment on the draft guidance. FDA received one comment on the draft guidance and that comment was considered as the guidance was finalized. Changes include editorial revisions to improve clarity regarding how and when data collection forms and standard operating procedures should be included with the protocol submission. The guidance announced in this notice finalizes the draft guidance dated February 2, 2011.

II. Significance of Guidance

This level 1 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 the topic. 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.

III. 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 this guidance have been approved under OMB control no. 0910–0032.

IV. 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.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

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