The estimate of the time required for record preparation and maintenance is based on Agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of type A medicated articles being manufactured, etc.) are derived from Agency records and experience.

Dated: January 28, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2355 Filed 2–2–11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0023]


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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#215) entitled “Target Animal Safety and Effectiveness Protocol Development and Submission.”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 (CVM), Office of New Animal Drug Evaluation (ONADE), to reduce the time to protocol concurrence. This guidance makes recommendations to aid in the preparation of protocols used to generate data to support new animal drug applications, specifically target animal safety and substantial evidence of effectiveness.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on this topic.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 (expiration date 04/30/2011).

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 draft guidance at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

Dated: January 28, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2355 Filed 2–2–11; 8:45 am]
I. Background

FDA is announcing the availability of a draft guidance for industry entitled “PET Drug Applications—Content and Format for NDAs and ANDAs.” This draft guidance revises the draft guidance entitled “Draft Guidance for Industry on PET Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products: Availability,” issued on March 10, 2000. The revised guidance is being issued again as a draft for comment because FDA’s perspective has changed significantly since issuance of the March 2000 draft guidance.

The draft guidance is intended to assist the manufacturers of certain PET drugs—fluodeoxyglucose (FDG) F 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection—in submitting NDAs and ANDAs in accordance with the FD&C Act and FDA regulations. The draft guidance explains that to continue marketing these PET drugs for clinical use, manufacturers of these drugs must submit NDAs of the type described in section 505(b)(2) of the FD&C Act (21 U.S.C. 355(b)(2)) or ANDAs under section 505(j) of the FD&C Act by December 12, 2011. The draft guidance further states when submission of a 505(b)(2) application or ANDA is appropriate and describes the information that manufacturers of these PET drugs should include in each type of application.

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 the submission of NDAs and ANDAs for PET drugs. 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) 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.

III. Electronic Access


Leslie Kux, Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2314 Filed 2–2–11; 8:45 am]