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]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0023]

Draft Guidance for Industry on "Target Animal Safety and Effectiveness Protocol Development and Submission," Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#215) entitled "Target Animal Safety and Effectiveness Protocol Development and Submission."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.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 19, 2011.

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 *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8318; e-mail: *angela.clarke@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (#215) entitled "Target Animal Safety and Effectiveness Protocol Development and Submission."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 CVM, 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. 2011–2315 Filed 2–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–1542; formerly Docket No. 00D–0892]

Draft Guidance on Positron Emission Tomography Drug Applications—Content and Format for New Drug Applications and Abbreviated New Drug 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 entitled "PET Drug Applications—Content and Format for NDAs and ANDAs." The draft guidance is intended to assist manufacturers of certain positron emission tomography (PET) drugs in submitting new drug applications (NDAs) or abbreviated new drug applications (ANDAs) in accordance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and FDA regulations. This draft guidance revises the draft guidance entitled "Draft Guidance for Industry on the Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products; Availability," issued on March 10, 2000. Elsewhere in this issue of the **Federal Register**, FDA is announcing a public meeting to assist applicants in preparing NDAs or ANDAs for fludeoxyglucose (FDG) 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection used in PET imaging.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 4, 2011.

ADDRESSES: Submit written requests for single copies of the draft 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 draft guidance document.

Submit electronic comments on the draft 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:

Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6164, Silver Spring, MD 20993–0002, 301–796–3416.

SUPPLEMENTARY INFORMATION:

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 the Content and Format of New 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—fludeoxyglucose (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

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: January 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0060]

Positron Emission Tomography; Notice of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to assist applicants in preparing new drug applications (NDAs) or abbreviated new drug applications (ANDAs) for fludeoxyglucose (FDG) 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection used in positron emission tomography (PET) imaging. By December 12, 2011, FDA expects all producers of PET drugs in commercial clinical use to submit applications for marketing approval. FDA recognizes that many PET drug producers are unfamiliar with the drug approval process. Accordingly, FDA is holding this public meeting to discuss the drug approval process and FDA's general inspection process. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a revised draft guidance for industry entitled "PET Drug Applications—Content and Format for NDAs and ANDAs" that will be used at the meeting to explain the drug approval process.

DATES: The meeting will be held on March 2, 2011, from 8:30 p.m. to 5 p.m. *See* section IV of this document for information on how to register for and attend the meeting. Submit either electronic or written comments on this document by March 7, 2011.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993–0002.

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:

Elizabeth Giaquinto, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 6164, Silver Spring, MD 20993–0002, 301–796–3416, FAX: 301–847–8752, e-mail: *PETDrugs@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, President Clinton signed the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) (FDAMA) into law. Section 121(c) of FDAMA directs FDA to regulate PET drugs. Section 121 requires FDA to develop appropriate procedures for the approval of PET drugs as well as current good manufacturing practice (CGMP) requirements for such drugs; to consult with patient advocacy groups, professional associations, manufacturers, and persons licensed to make or use PET drugs in the process of establishing these procedures and requirements; and to not require the submission of NDAs or ANDAs for compounded PET drugs that are not adulterated as described in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) for a period of 4 years after the date of enactment of FDAMA or 2 years after the date FDA adopts special approval procedures and CGMP