is reduced because the respondents do not submit a full report for each event they report in a quarterly summary report.

The Agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the MDR requirements as part of their internal quality control system. There are an estimated 30,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints, under § 803.18(d).

The Agency has estimated that on average 220 user facilities, importers, and manufacturers would annually be required to establish new procedures, or revise existing procedures, in order to comply with this provision.

Therefore, FDA estimates the one-time burden to respondents for establishing or revising procedures under § 803.17 to be 2,200 hours (220 respondents x 10 hours). For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers, not required to revise their written procedures to comply with this provision, are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

Under § 803.18, 30,000 respondents represent distributors, importers, and other respondents to this information collection. FDA estimates that it should take them approximately 1.5 hours to complete the recordkeeping requirement for this section. Total hours for this section equal 45,000 hours.

Dated: February 9, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3344 Filed 2–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0081]

Draft Guidance on Investigational New Drug Applications for Positron Emission Tomography Drugs; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs.'' The draft guidance is intended to assist manufacturers of PET drugs in submitting investigational new drug applications (INDs).

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 May 14, 2012.

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: Kyong (Kaye) Kang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2352, Silver Spring, MD 20993, 301–796–2050.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Investigational New Drug Applications for Positron Emission Tomography (PET) drugs.'' The draft guidance summarizes the IND process for PET drugs, makes recommendations for how to submit an IND, provides advice on expanded access options for investigational PET drugs, and describes the process for requesting permission to charge for an investigational PET drug.

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 INDs 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. 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. Paperwork Reduction Act of 1995

This draft 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). INDs and requests to charge for a drug under an IND are submitted to FDA under part 312 (21 CFR part 312). NDAs and ANDAs are submitted to FDA under §§ 314.50 and 314.94 (21 CFR 314.50 and 3.14.94). The collections of information in part 312 and in §§ 314.50 and 314.94 have been approved under OMB control numbers 0910–0014, 0910–0653, 0910–0651, and 0910–0001.

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: February 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3319 Filed 2–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0805]

Dermatologic and Ophthalmic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the meeting of the Dermatologic and Ophthalmic Drugs

Advisory Committee. This meeting was announced in the **Federal Register** of November 17, 2011 (76 FR 71349). The amendment is being made to reflect a change in the *Date and Time, Agenda,* and *Procedure* portions of the document. We are cancelling (Topic 1), the portion of the meeting relating to the appropriate types of clinical evidence for developing anti-inflammatory drugs for the treatment of postoperative inflammation and reduction of ocular (eye) pain in patients who have undergone ocular surgery. The portion of the meeting (Topic 2), relating to the appropriateness of marketing a single bottle of anti-inflammatory ophthalmic products for use in both eyes for post-surgical indications as it relates to the potential risk for infection will still be held on the same date (February 27, 2012), the time for the meeting has been changed to 9 a.m. to 3 p.m.

FOR FURTHER INFORMATION CONTACT: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. WO31–2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *DODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301 443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 17, 2011, FDA announced that a meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee would be held on February 27, 2012. On page 71349, in the first column, the *Date and Time* portion of the document is changed to read as follows:

Date and Time: The meeting will be held on February 27, 2012, from 9 a.m. to 3 p.m.

On page 71349, in the second column, the *Agenda* portion of the document is changed to read as follows:

Agenda: The committee will be asked to comment on the appropriateness of marketing a single bottle of anti-inflammatory ophthalmic products for use in both eyes for post-surgical indications as it relates to the potential risk for infection. The FDA's Center for Drug Evaluation and Research would like the advisory committee to provide advice on the potential risk and approaches to mitigating that risk, including limits to fill size where appropriate.

On page 71349, in the third column, the third sentence in the Procedure portion of the document is changed to read as follows:

Procedure: Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 8, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–3343 Filed 2–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Anti-mesothelin Targeted Immunotoxins for the Treatment of Cancer

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in US Patent application 61/535,668 entitled ''Pseudomonas Exotoxin A with Less Immunogenic B Cell Epitopes'' [HHS Ref. E–263–2011/0–US–01], US Patent application 61/495,085 entitled ''Pseudomonas Exotoxin A with Less Immunogenic T Cell Epitopes'' [HHS Ref. E–174–2011/0–US–01], US Patent application 61/483,531 entitled ''Recombinant Immunotoxin Targeting Mesothelin'' [HHS Ref. E–117–2011/0–US–01], U.S. Patent Application 61/241,620 entitled ''Development of an Immunotoxin in Which All B–Cell Epitopes Have Been Removed and Which Has High Cytotoxic Activity'' [HHS Ref. E–269–2009/0–US–01], U.S. Patent Application 60/969,929 entitled ''Deletions in Domain II of Pseudomonas Exotoxin A That Reduce Non-Specific Toxicity'' [HHS Ref. E–292–2007/0–US–01], U.S. Patent Application 60/703,798 entitled ''Mutated Pseudomonas Exotoxins with Reduced Antigenicity'' [HHS Ref. E–262–2005/0–US–01], U.S. Patent Application 60/160,071 entitled ''Immunoconjugates Having High Binding Affinity'' [HHS Ref. E–139–1999/0–US–01], U.S. Patent Application 60/067,175 entitled ''Antibodies, Including Fv Molecules, and Immunoconjugates Having High Binding Affinity for Mesothelin and Methods for Their Use'' [HHS Ref. E–021–1998/0–US–01], U.S. Patent Application 60/010,166 entitled ''Molecular Cloning of Mesothelin, a Differentiation Antigen Present on Mesothelium, Mesotheliomas and Ovarian Cancers'' [HHS Ref. E–002–1996/0–US–01], PCT Application PCT/US97/00224 entitled ''Mesothelin Antigen and Methods and Kits for Targeting It'' [HHS Ref. E–002–1996/1–PCT–01], U.S. Patent 5,747,654 entitled ''Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity'' [HHS Ref. E–163–1993/0–US–01], PCT application PCT/US96/16327 entitled ''Immunotoxin Containing A Disulfide-Stabilized Antibody Fragment'' [HHS Ref. E–163–1993/2–PCT–01], and all continuing applications and foreign counterparts, to Hoffman-La Roche, Inc. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to:

The use of anti-mesothelin targeted immunotoxins for the treatment of mesothelin-expressing cancers, wherein the immunotoxins have: (1) A targeting domain containing the complementary determining regions (CDR) of the SS1 antibody and (2) a *Pseudomonas* exotoxin A (''PE'') toxin domain that is (a) lysosomal protease resistant (PE–LR) and (b) lacks at least one major B-cell epitope due to the alteration of an amino acid. The immunotoxin may include additional alterations to B-cell and T-cell epitopes for reduction of immunogenicity, as well as a peptide linker sequence.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before March 15, 2012 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, PhD, Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4632; Facsimile: (301) 402–0220; Email: *lambertsond@od.nih.gov.*

SUPPLEMENTARY INFORMATION: These inventions concern immunotoxins which are targeted to mesothelin-expressing cancer cells, and methods of