rule entitled ''Implementation of Device Registration and Listing Requirements Enacted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Medical Device User Fee and Modernization Act of 2002, and Title II of the Food and Drug Administration Amendments Act of 2007.''

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
807.20(a)(5) [2]—Submittal of manufacturer information by initial importers	3673	8,594	1	8,594	1.75	15,040
807.20(a)(5) [3]—Submittal of manufacturer information by initial importers	3673	8,594	3	25,782	0.1	2,578
807.21(a) [3]—Creation of electronic system account	3673	3,559	1	3,559	0.5	1,780
807.21(b) [2]—Annual request for waiver from electronic registration & listing	.....	14	1	14	1	14
807.21(b) [3]—Initial request for waiver from electronic registration & listing	.....	4	1	4	1	4
807.22(a) [3]—Initial registration & listing	3673	3,539	1	3,539	0.5	1,770
807.22(b)(1) [3]—Annual registration	3673	20,355	1	20,355	0.75	15,266
807.22(b)(2) [3]—Other updates of registration	3673	4,176	1	4,176	0.5	2,088
807.22(b)(3) [3]—Annual update of listing information	3673	19,875	1	19,875	1	19,875
807.26(e) [3]—Labeling & advertisement submitted at FDA request	.....	71	1	71	1	71
807.34(a) [2]—Initial registration & listing when electronic filing waiver granted	.....	14	1	14	1	14
807.34(a) [3]—Annual registration & listing when electronic filing waiver granted	.....	4	1	4	1	4
807.40(b)(2) [3]—Annual update of US agent information	3673	1,615	1	1,615	0.5	808
807.40(b)(3) [3]—US agent responses to FDA requests for information	3673	1,535	1	1,535	0.25	384
807.41(a) [3]—Identification of initial importers by foreign establishments	3673	10,329	1	10,329	0.5	5,165
807.41(b) [3]—Identification of other parties that facilitate import by foreign establishments	3673	10,329	1	10,329	0.5	5,165
Total on-time burden	.....	.....	.....	.....	.....	15,068
Total recurring burden	.....	.....	.....	.....	.....	54,958

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.
[3] Recurring burden.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
807.25(d) [2]—List of Officers, Directors & Partners	23,806	1	23,806	0.25	5,952
807.26 [2]—Labeling & Advertisements Available for Review	11,746	4	46,984	0.5	23,492
Total	.....	.....	.....	.....	29,444

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

Dated: October 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27199 Filed 10–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3517]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' The draft guidance describes FDA's interim regulatory policy regarding the use of bulk drug substances by licensed pharmacists in State-licensed pharmacies or Federal facilities and by licensed physicians to compound human drug products while FDA develops the list of bulk drug substances that can be used in compounding under the Federal Food, Drug, and Cosmetic Act (FD&C Act). When final, the guidance will reflect the Agency's current thinking on the issues addressed by the guidance.

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 the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 28, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–3517 for ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Draft Guidance; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993–0002, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Sections 503A of the Federal Food, Drug, and Cosmetic Act.'' Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act: Section 505 (concerning the approval of drugs under new drug applications or abbreviated new drug applications); section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and section 501(a)(2)(B) (concerning current good manufacturing practice requirements).

One of the conditions that must be met for a compounded drug product to qualify for these exemptions is that a licensed pharmacist or licensed physician compounds the drug product using bulk drug substances that: (1) Comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A. (See section 503A(b)(1)(A)(i) of the FD&C Act).

This guidance describes the conditions under which FDA does not intend to take action against a licensed pharmacist or licensed physician for compounding a drug product from a bulk drug substance that is not the subject of an applicable USP or NF monograph, is not a component of an FDA-approved drug, or does not appear on the list of bulk drug substances that can be used in compounding under section 503A(b)(1)(A)(i)(III) of the FD&C Act by a licensed pharmacist or licensed physician while FDA is developing the list.

Elsewhere in this issue of the **Federal Register**, the Agency is making available for public comment a draft guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act,'' which describes conditions under

which FDA does not intend to object to the compounding of a drug product from certain bulk drug substances by an outsourcing facility while FDA develops the list of bulk drug substances that can be used in compounding under section 503B(a)(2)(A)(i) of the FD&C Act.

The final guidance ''Pharmacy Compounding of Human Drug Products Under Section 503A of the FD&C Act,'' (503A Final Guidance) published in 2014 (79 FR 37742; July 2, 2014), states, ''Until a bulk drug substances list is published in the **Federal Register** as a final rule, human drug products should be compounded using only bulk drug substances that are components of drugs approved under section 505 of the FD&C Act, or are the subject of USP or NF monographs.'' Because this draft interim guidance proposes to change the Agency's policy relating to compounding with bulk drug substances while FDA develops a list of bulk drug substances that can be used in compounding, FDA is adding a footnote to the 503A Final Guidance referencing this draft interim guidance. Once this draft interim guidance is finalized, FDA intends to remove that footnote from the 503A Final Guidance and cross-reference the final interim guidance as establishing the policy for compounding with bulk drug substances during the development of the 503A bulks list. The footnote is being added to the 503A Final Guidance as a Level 2 change under 21 CFR 10.115 because the final interim guidance, rather than the footnote to the 503A Final Guidance, will set forth the actual change in policy. Accordingly, comments on the proposed change in policy are being solicited as part of this Notice of Availability on the draft interim guidance.

II. Electronic Access

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

Dated: October 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27269 Filed 10–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute, Special Emphasis Panel; T32 Training Program for Institutions that Promote Diversity.

Date: November 16, 2015.

Time: 2:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Stephanie L Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301–443–8784, *constantsl@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 22, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–27325 Filed 10–26–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Clinical and Epidemiological Applications: Retina, Glaucoma and Neuro-Ophthalmology.

Date: December 10, 2015.

Time: 8:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, Division of Extramural Research, 5635 Fishers Lane, Suite 1300, Rockville, MD 20892, 301–451–2020, *hoshawb@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: October 22, 2015.

Natasha Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–27324 Filed 10–26–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01).

Date: November 24, 2015.