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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Number of Completes	640	1	640	1	640
Main Study					
Number to Complete the Screener (Assumes 50% Eligible).	2,112	1	2,112	0.08 (5 minutes)	169
Number of Completes	1,056	1	1,056	1	1,056
Total					1,967.40

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

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

References

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13. Sommers MS, Tye-Murray N, Spehar B, Auditory-Visual Speech Perception and Auditory-Visual Enhancement in Normal-Hearing Younger and Older Adults, *Ear and Hearing,* 2005;26(3):263–75.
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Dated: *June 18, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15557 Filed 6–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0248]

Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products; Guidance for Industry; 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 ''Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products.'' It replaces the draft of the same name that was published on March 14, 2014. This guidance clarifies FDA requirements and regulations pertaining to allowable excess volume in injectable vials and reinforces the importance of appropriate fill volumes and labeled vial fill sizes for injectable drug and biological products.

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. 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: Pallavi Nithyanandan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD

20993–0002, 301–796–7546; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products.'' This guidance replaces the draft guidance of the same name that published in the **Federal Register** of March 14, 2014 (79 FR 14517). FDA is concerned that injectable vial misuse, including unsafe handling and injection techniques, has led to an increase in vial contamination and an increased risk of bloodborne illness transmission between patients. This guidance clarifies the FDA requirements and regulations pertaining to allowable excess volume in injectable vials and describes when justification is needed for a proposed excess volume in an injectable drug or biological product. This guidance also discusses the importance of appropriate fill volume and recommends that labeled vial fill sizes be appropriate for the use and dosing of the drug and biological product.

In the **Federal Register** of March 14, 2014 (79 FR 14517), a draft guidance was published entitled ''Draft Guidance for Industry on Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products; Availability.'' We have carefully reviewed and considered the comments that were received on the draft guidance and have made changes for clarification.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on allowable excess fill volume and labeled vial fill size for injectable drug and biological products packaged in vials and ampules. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

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

Dated: June 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15637 Filed 6–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of a meeting of the Board of Scientific Counselors, National Center for Biotechnology Information.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL LIBRARY OF MEDICINE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Center for Biotechnology Information.

Date: December 1, 2015.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: Program Discussion.

Place: National Library of Medicine, Building 38, 2nd Floor, The Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892.

Closed: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Library of Medicine, Building 38, 2nd Floor, The Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892.

Open: 2:00 p.m. to 3:00 p.m.

Agenda: Program Discussion.

Place: National Library of Medicine, Building 38, 2nd Floor, The Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: David J. Lipman, MD, Director, National Center of Biotechnology Information, National Library of Medicine, Department of Health and Human Services, Building 38A, Room 8N805, Bethesda, MD 20892, 301–435–5985, *dlipman@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS).

Dated: June 19, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–15602 Filed 6–24–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

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 meetings.