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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Center Activity	Number of respondents (investigational applications)	Number of respondents (marketing applications)	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
CDER						
New Applications (IND)	1,752		1	1,752	15/60	438
Clinical Protocol Amendments (IND)	11,769		1	11,769	15/60	2,943
New Marketing Applications/Resubmissions (NDA/BLA)		157	1	157	45/60	118
Clinical Amendments to Marketing Applications		1,466	1	1,466	45/60	1,100
Efficacy Supplements/Resubmissions		166	1	166	45/60	125
CBER						
New Applications (IND)	281		1	281	15/60	70
Clinical Protocol Amendments (IND)	1,471		1	1,471	15/60	368
New Marketing Applications/Resubmissions		8	1	8	45/60	6
Clinical Amendments to Marketing Applications		17	1	17	45/60	13
Efficacy Supplements/Resubmissions (BLA only)		25	1	25	45/60	19
CDRH						
New Marketing Applications (includes PMAs, HDEs, Supplements and 510(k)s expected to contain clinical data)		892	1	892	45/60	669
OGD						
Original Applications		854	1	854	45/60	641
BE Supplements/Amendments		495			45/60	372
Total						6,882

[1] There are no capitol costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

Dated: May 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–11073 Filed 5–5–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0126]

Guidance for Industry on the Submission of Summary Bioequivalence Data for 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 guidance for industry entitled "Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications." The guidance is intended to assist abbreviated new drug application (ANDA) applicants in complying with the requirements in the final rule on the submission of bioequivalence data that published in the **Federal Register** in January 2009 (74 FR 2849, January 16, 2009). The final rule requires ANDA applicants to submit data from all bioequivalence studies (BE studies) the applicant conducts on a drug product formulation submitted for approval, including both studies that demonstrate and studies that fail to demonstrate that a generic product meets the current bioequivalence criteria. The guidance provides recommendations to applicants planning to include BE studies for submission in ANDAs and is applicable to BE studies conducted during both preapproval and postapproval periods.

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, 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 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: Aida L. Sanchez, Center for Drug Evaluation and Research (HFD–650),

Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8782.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Submission of Summary Bioequivalence Data for ANDAs." The guidance provides recommendations to applicants planning to include BE studies for submission in ANDAs. The guidance provides information on the following subjects:

- Types of ANDA submissions covered by the regulations on BE studies;
- Recommended format for summary reports of BE studies; and
- Types of formulations the Agency considers to be the same drug product formulation for different dosage forms based on differences in composition.

The guidance is applicable to BE studies conducted for ANDAs during both preapproval and postapproval periods.

On April 17, 2009, FDA announced the availability of the draft version of this guidance (74 FR 17872). The public comment period closed on July 16, 2009. A few comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. Changes to the guidance were minor and made to clarify statements in the draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on submission of summary bioequivalence data for ANDAs. 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. Paperwork Reduction Act of 1995

This guidance refers to information collection provisions 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 314.94(a)(7), 314.96(a)(1), and 314.97 have been approved under OMB control number 0910–0630.

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: May 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–11102 Filed 5–5–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse And Alcoholism; Notice of Meeting.

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

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 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 Advisory Council on Alcohol Abuse and Alcoholism.

Date: June 8–9, 2011.

Closed: June 8, 2011, 5:30 p.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Open: June 9, 2011, 9 a.m. to 3 p.m.

Agenda: Presentation and other business of the council.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Abraham P. Bautista, PhD, Executive Secretary, National Institute on Alcohol Abuse & Alcoholism National Institutes of Health, 5635 Fishers Lane, Rm 2085, Rockville, Md 20852, 301–443–9737, *bautistaa@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *silk.nih.gov/silk/niaaa1/about/roster.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: May 2, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–11170 Filed 5–5–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 on Alcohol Abuse and Alcoholism Initial Review Group, Epidemiology, Prevention and Behavior Research Review Subcommittee.

Date: July 19, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.