each year, 5 of which FDA expects to be HDEs. This estimate is based on the average of FDA's receipt of new PMA applications. The Agency estimates that 10 of the estimated 40 original PMA submissions will fail to provide the required pediatric use information and their sponsors will therefore be required to submit PMA amendments. The Agency also expects to receive approximately 700 supplements that will include the pediatric use information required by section 515A(a) of the FD&C Act and part 814 (21 CFR part 814).

All that is required is to gather, organize, and submit information that is readily available, using any approach that meets the requirements of section 515A(a) of the FD&C Act and part 814. We believe that because the applicant is required to organize and submit only readily available information, no more than 8 hours will be required to comply. Furthermore, because supplements may include readily available information on pediatric populations by referencing a previous submission, FDA estimates the average time to obtain and submit the required information in a supplement to be 2 hours. FDA estimates that the total estimated burden is 1,760 hours.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pediatric information in an original PMA or PDP—814.20(b)(13)	30	1	30	8	240
Pediatric information in a PMA amendment—814.37(b)(2)	10	1	10	8	80
Pediatric information in a PMA supplement—814.39(c)(2)	700	1	700	2	1,400
Pediatric information in an HDE—814.104(b)(6)	5	1	5	8	40
Total					1,760

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

Dated: December 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30243 Filed 12–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Extension of Effective Date of NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

The National Institutes of Health (NIH) is extending the effective date of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research from May 25, 2017, to September 25, 2017. A copy of the NIH Policy was published in the **Federal Register** on June 21, 2016 (81 FR 40325). See *https://www.gpo.gov/fdsys/pkg/FR-2016-06-21/pdf/2016-14513.pdf.* Guidance and Frequently Asked Questions to assist in the implementation of the policy will soon be available at *http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review.*

For further information contact the NIH Office of Science Policy, Telephone: 301–496–9838, Email: *SingleIRBPolicy@mail.nih.gov.*

Dated: December 12, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–30398 Filed 12–15–16; 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 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 and/or contract proposals, 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: February 9, 2017.

Closed: 9:00 a.m. to 9:30 a.m.

Agenda: BSC Report: Evaluation of the NIAAA Intramural Program.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Terrace Conference Rooms, Bethesda, MD 20892.

Closed: 9:40 a.m. to 10:50 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Terrace Conference Rooms, Bethesda, MD 20892.

Open: 11:00 a.m. to 3:15 p.m.

Agenda: Presentations and other business of the Council.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Terrace Conference Rooms, Bethesda, MD 20892.

Contact Person: Abraham P. Bautista, Ph.D., Executive Secretary, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, 301–443–9737 *bautista@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.

Information is also available on the Institute's/Center's home page: *http://www.niaaa.nih.gov/AboutNIAAA/AdvisoryCouncil/Pages/default.aspx,* where an agenda and any additional information for the meeting will be posted when available.