Submissions,'' publicly viewable at *https://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 *https://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 *https://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 Office of Policy, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, Bldg. 32, Rm. 4238, 10903 New Hampshire Ave., Silver Spring, MD, 20993. 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: Robert Berlin, Office of Policy, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, Bldg. 32, Rm. 4238, 10903 New Hampshire Ave., Silver Spring, MD, 20993, 301–796–8828, *robert.berlin@fda.hhs.gov.* Alternate contact: Office of Policy, 301–796–4830.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for the public and FDA staff entitled ''Gifts to FDA: Evaluation and Acceptance.'' The Secretary of HHS has the authority to accept conditional or unconditional gifts on behalf of the United States. The Secretary has delegated this gift authority to the Commissioner of Food and Drugs. This guidance provides the process and principles we will use in implementing this authority.

FDA will consider gifts from all sources except the Reagan-Udall Foundation (RUF) on a case-by-case basis using a balancing test, described in the guidance. While any person may offer a gift, there are five reasons we should reject a gift without additional evaluation. We should not accept a gift if: (1) The donor imposes conditions that are illegal, are contrary to public policy, are unreasonable to administer, are contrary to FDA's current policies and procedures, or are contrary to generally accepted public standards; (2) the donor requires us to provide the donor with some privilege, concession, or other present or future benefit in return for the gift; (3) a debarred entity offers the gift; (4) a different authority or financial mechanism applies; or (5) the total costs associated with acceptance are expected to exceed the cost of purchasing a similar item and the cost of normal care and maintenance.

In the **Federal Register** of June 29, 2016 (81 FR 42365), FDA announced the availability of a draft guidance entitled ''Gifts to FDA: Evaluation and Acceptance: Evaluation and Acceptance.'' FDA received one comment expressing concern regarding the policy described in the guidance. It appears the commenter may have misunderstood the policy and incorrectly believed that gifts would not be limited, would be unreported, and would be provided to Federal employees themselves. As explained in the guidance, that is not the case. Rather, the recipients of any gifts would be the Agency, gifts are extensively reviewed to ensure receipt would be appropriate, and the Agency intends to publish a summary of received gifts. The Agency has made only minor changes to the guidance to clarify that the evaluation of gifts from RUF will reflect RUF's unique role in support of the Agency and the statutory safeguards in 21 U.S.C. 379dd. In addition, the discussion of restrictions on funds for travel has been clarified to better reflect the scope of statutes and policies governing the use of non-Agency funds for travel.

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 this matter. 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. Electronic Access

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

Dated: December 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30312 Filed 12–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3995]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the requirement for submission of information on pediatric subpopulations

that suffer from a disease or condition that a device is intended to treat, diagnose, or cure.

DATES: Submit either electronic or written comments on the collection of information by February 14, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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–2016–N–3995 for ''Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended to Treat, Diagnose, or Cure.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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 *https://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 *https://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.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure—21 CFR Part 814—OMB Control Number 0910–0748—Extension

Section 515A(a) of the FD&C Act requires applicants who submit certain medical device applications to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. The information submitted will allow FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure and the review time for each such device application.

These requirements apply to applicants who submit humanitarian device exemption requests (HDEs), premarket approval applications (PMAs) or PMA supplements, or a product development protocol (PDP).

FDA expects to receive approximately 45 original PMA/PDP/HDE applications

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.