LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 7.5 mg/vial and 7.5 mg/vial, are the subject of NDA 020263, held by Abbvie Endocrine, Inc., and initially approved on April 16, 1993. LUPRON DEPOT–PED is indicated for treatment of children with central precocious puberty.

In a report dated January 30, 1999, Abbvie notified FDA that LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT–PED (leuprolide acetate for depot suspension), Injectable 7.5 mg/vial and 7.5 mg/vial, were being discontinued, and FDA moved the drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

Joan Janulis, on behalf of Lachmann Consultant Services, Inc., submitted a citizen petition dated November 4, 2013 (Docket No. FDA–2013–P–1510), under 21 CFR 10.30, requesting that the Agency determine whether LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; or LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; and LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to LUPRON DEPOT–PED, Injectable 3.75 mg/vial and 7.5 mg/vial; or LUPRON DEPOT–PED, Injectable 7.5 mg/vial and 7.5 mg/vial, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 14, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–19713 Filed 8–19–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1179]

Request for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels and Request for Notification From Consumer Organizations Interested in Participating in the Selection Process for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization. Nominations will be accepted for current vacancies and for those that will or may occur through December 2014.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to the FDA (see **ADDRESSES**) by September 19, 2014, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by September 19, 2014.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should submit their information electronically to *kimberly.hamilton@fda.hhs.gov* or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, FAX 301–847–8640.

Consumer representative nominations should be submitted electronically by logging into the FDA advisory Committee Membership Nomination Portal at *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, or by fax to 301–847–8640. Additional information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER GENERAL INFORMATION CONTACT: Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5117, Silver Spring, MD 20993–0002, 301–796–6319, email: *kimberly.hamilton@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: For questions relating to specific advisory committees or panels, contact the following persons listed in table 1:

TABLE 1—ADVISORY COMMITTEE CONTACTS

Contact person	Committee/panel
Jamie Waterhouse, Center for Devices and Radiological Health, Office of Device Evaluation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1611, Silver Spring, MD 20993, 301–796–3063, FAX: 301–796–3063, email: *Jamie.Waterhouse@fda.hhs.gov.*	Circulatory System Devices Panel.
Karen Strambler, Center for Food Safety and Applied Nutrition, FDA College Park, CPK1, Rm. 1C016, College Park, MD 20740, 240–402–2589, FAX: 301–436–2637, email: *Karen.Strambler@fda.hhs.gov.*	Food Advisory Committee.
Patricio Garcia, Center for Devices and Radiological Health, Office of Device Evaluation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3631, Silver Spring, MD 20903, 301–796–6875, FAX: 301–847–8120, email: *Patricio.Garcia@fda.hhs.gov.*	General and Plastic Surgery Devices Panel.
Sara J. Anderson, LCDR, U.S. Public Health Service, Center for Devices and Radiological Health, Office of Device Evaluation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1643, Silver Spring, MD 20903, 301–796–7047, FAX: 301–847–8122, email: *Sara.Anderson@fda.hhs.gov.*	Hematology and Pathology Devices Panel, Orthopaedic and Rehabilitation Devices Panel, National Mammography and Quality Assurance Advisory Committee.
Pamela Scott, Center for Devices and Radiological Health, Office of the Center Director, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3611, Silver Spring, MD 20993, 301–796–5433, FAX: 301–847–8510, email: *Pamela.Scott@fda.hhs.gov.*	Medical Devices Dispute Resolution Panel.
Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993–0002, 301–796–6639, FAX: 301–847–8122, email: *Shanika.Craig@fda.hhs.gov.*	Obstetrics and Gynecology Devices Panel.
Walter Ellenberg, Office of the Commissioner, Office of Pediatric Therapeutics, Food and Drug Administration, Bldg. 32, Rm. 5154, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0885, FAX: 301–847–8640, email: *Walter.Ellenberg@fda.hhs.gov.*	Pediatrics Advisory Committee.
Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2438, Silver Spring, MD 20993–0002, 301–796–9005, FAX: 301–847–8533, email: *Kalyani.Bhatt@fda.hhs.gov.*	Psychopharmacologic Drugs Advisory Committee, Reproductive Health Drugs Advisory Committee.

FDA is requesting nominations for voting and/or nonvoting consumer representatives for the vacancies listed in table 2:

TABLE 2—COMMITTEE DESCRIPTIONS, TYPE OF CONSUMER REPRESENTATIVE VACANCY AND APPROXIMATE DATE NEEDED

Committee/panel/areas of expertise needed	Current & upcoming vacancies	Approximate date needed
Circulatory System Devices—Knowledgeable in the safety and effectiveness of marked and investigational devices for use in the circulatory and vascular systems.	Nonvoting	Immediately.
Food Advisory Committee—Knowledgeable in the fields of physical sciences, biological and life sciences, food science, risk assessment, nutrition, food technology, molecular biology, and other relevant scientific and technical disciplines.	Voting	Immediately.
General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee—Knowledgeable in the fields of general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic and endoscopic surgery; biomaterials, lasers, wound healing, and quality of life issues.	1-Nonvoting	9/1/2014.
Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee—Knowledgeable in the fields of hematology, hematopathology, coagulation and homeostasis, hematological oncology, and gynecological oncology.	1-Nonvoting	Immediately.
Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee—Knowledgeable experts with broad, cross-cutting scientific, clinical, analytical, or mediation skills.	1-Nonvoting	10/1/2014.
National Mammography Quality Assurance Advisory Committee—Knowledgeable in clinical practice, research specialization, or professional work that has a significant focus on mammography.	1-Nonvoting.	
Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee—Knowledgeable in the fields of perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; obstetrics/gynecology devices; gynecology in the older patient; midwifery; labor and delivery nursing.	1-Nonvoting	Immediately.
Orthopaedic and Rehabilitation Devices Panel—Knowledgeable in data concerning the safety and effectiveness of marketed and investigational orthopaedic and rehabilitation devices.	1-Nonvoting	Immediately.
Pediatrics Advisory Committee—Knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics.	1-Voting	Immediately.
Psychopharmacologic Drugs Advisory Committee—Knowledgeable in the fields of psychopharmacology, psychiatry, epidemiology or statistics, and related specialties.	1-Voting	Immediately.
Bone, Reproductive, and Urologic Drugs Advisory Committee—Knowledgeable in the fields of obstetrics, gynecology, endocrinology, pediatrics, epidemiology, or statistics and related specialties.	1-Voting	Immediately.

I. Functions

A. Certain Panels of the Medical Devices Advisory Committee

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (the FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories, advises on any possible risks to health associated with the use of devices, advises on formulation of product development protocols, reviews premarket approval applications for medical devices, reviews guidelines and guidance documents, recommends exemption of certain devices from the application of portions of the FD&C Act, advises on the necessity to ban a device, and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

B. Food Advisory Committee

The Committee provides advice to the Commissioner of Food and Drugs and other appropriate officials, on emerging food safety, food science, nutrition, and other food-related health issues that the FDA considers of primary importance for its food and cosmetics programs. The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food or cosmetic related issues; (2) the safety of new foods and food ingredients; (3) labeling of foods and cosmetics; (4) nutrient needs and nutritional adequacy; and (5) safe exposure limits for food contaminants. The Committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

C. National Mammography and Quality Assurance Advisory Committee

The Committee reviews and evaluates: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

D. Pediatric Advisory Committee

The Committee advises and makes recommendations to the Commissioner of Food and Drugs regarding: (1) Pediatric research; (2) identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics; (4) pediatric labeling disputes; (5) pediatric labeling changes; (6) adverse event reports for drugs granted pediatric exclusivity and any safety issues that may occur; (7) any other pediatric issue or pediatric labeling dispute involving FDA regulated products; (8) research involving children as subjects; and (9) any other matter involving pediatrics for which FDA has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by the Department of Health and Human Services.

E. Psychopharmacologic Drugs Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

F. Bone, Reproductive, and Urologic Drugs Advisory Committee

Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties.

G. The Medical Devices Dispute Resolution Panel

The Panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

II. Criteria for Members

Persons nominated for membership as consumer representatives on committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations; (2) be able to analyze technical data; (3) understand research design; (4) discuss benefits and risks; and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee, serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations, and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the

selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or résumé. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Nominations should include a cover letter and a current curriculum vitae or résumé for each nominee, including a current business and/or home address, telephone number, email address if available, and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations should also specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

Dated: August 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19696 Filed 8–19–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance Program; Negotiation Cooperative Agreement; Correction

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on July 29, 2014, for the FY 2014 Office of Tribal Self-Governance Program, Negotiation Cooperative Agreement Announcement. The notice contained an incorrect date.

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy Marshall, Policy Analyst, Office of Tribal Self-Governance, Indian Health Service, 801 Thompson Avenue, Suite 240, Rockville, MD 20852, Telephone (301) 443–7821. (This is not a toll-free number.)

Correction

In the **Federal Register** of July 29, 2014, in FR Doc. 2014–17800, on page 44049, in the second column, under the heading Key Dates, the correct date should read as follows:

Signed Tribal Resolutions Due Date: September 8, 2014.

Dated: August 13, 2014.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2014–19700 Filed 8–19–14; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance Program; Planning Cooperative Agreement; Correction

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on July 29, 2014, for the FY 2014 Office of Tribal Self-Governance Program, Planning Cooperative Agreement Announcement. The notice contained an incorrect date.

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy Marshall, Policy Analyst, Office of Tribal Self-Governance, Indian Health Service, 801 Thompson Avenue, Suite 240, Rockville, MD 20852, Telephone (301) 443–7821. (This is not a toll-free number.)

Correction

In the **Federal Register** of July 29, 2014, in FR Doc. 2014–17801, on page 44043, in the first column, under the heading Key Dates, the correct date should read as follows:

Signed Tribal Resolutions Due Date: September 8, 2014.

Dated: August 13, 2014.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2014–19699 Filed 8–19–14; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Chimpanzee Research Use Form (OD)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 13, 2014, page 27318, and allowed 60 days for public comment. The NIH received two requests to view the form and one comment expressing the opinion that chimpanzee research should be discontinued but did not receive any public comments on the form itself. The purpose of this notice is to allow an additional 30 days for public comment. The NIH Office of the Director (OD), Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the OMB Office of Regulatory Affairs at *OIRA_submission@omb.eop.gov;* or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.