

GuidanceDocuments/default.htm.

Guidance documents are also available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>. Persons unable to download an electronic copy of “Postmarket Management of Cybersecurity in Medical Devices” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400044 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 part 803 (medical device reporting) have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 806 (reports of corrections and removals) have been approved under OMB control number 0910–0359; the collections of information in 21 CFR part 810 (medical device recall authority) have been approved under OMB control number 0910–0432; the collections of information in 21 CFR part 814 (premarket approval) have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 (quality system regulations) have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 822 (postmarket surveillance of medical devices) have been approved under OMB control number 0910–0449.

V. Other Issues for Consideration

The Agency invites comments on the “Postmarket Management of Cybersecurity in Medical Devices” draft guidance, in general, and on the following questions, in particular:

- What factors contribute to a manufacturer’s decision whether or not to participate in an ISAO?
- In the draft guidance, the FDA is proposing its intention to not enforce certain regulatory requirements for manufacturer’s that are “participating members” of an ISAO. Should FDA define what it means to be a “participating member” of an ISAO and if so, how should such participation be verified?

- What are the characteristics (participation, expertise, policies, and practices) of an ISAO that would make it qualified to participate in the sharing and analysis of medical device cybersecurity vulnerabilities? What are the benefits and disadvantages of FDA “recognizing” specific ISAOs as possessing specialized expertise relevant to sharing and analysis of medical device vulnerabilities and what should such recognition entail?

- When cybersecurity vulnerability information is not reported to FDA, what information should be reported to the ISAO, and when?

- How should the FDA interact with ISAOs, manufacturers, HDOs, security researchers and other stakeholders to maximize the sharing of information concerning cybersecurity threats while maintaining confidentiality and protecting commercial confidential information?

Dated: January 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01172 Filed 1–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Arthritis Advisory Committee; Notice of Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on January 19, 2016 (81 FR 2873). The document announced an “Arthritis Advisory Committee” meeting and contained an incorrect date for individuals requesting oral presentations, and for FDA notifying individuals regarding their request to speak at the meeting. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533.

SUPPLEMENTARY INFORMATION: In FR Doc. 2016–00823, appearing on page 2873 in the **Federal Register** of Tuesday, January 19, 2016, the following corrections are made:

1. On page 2873, in the third column, in the “*Procedure*” paragraph, the fourth sentence is corrected to read “Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 28, 2016.”

2. On page 2873, in the third column, in the “*Procedure*” paragraph, the last sentence is corrected to read “The contact person will notify interested persons regarding their request to speak by January 29, 2016.”

Dated: January 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01248 Filed 1–21–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advisory Committee; Pharmaceutical Science and Clinical Pharmacology Advisory Committee (Formerly Known as the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology), Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee (formerly known as the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Pharmaceutical Science and Clinical Pharmacology Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the January 22, 2018.

DATES: Authority for the Pharmaceutical Science and Clinical Pharmacology Advisory Committee will expire on January 22, 2018, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Avenue, Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, *ACPS-CP@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Pharmaceutical Science and Clinical Pharmacology Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee reviews and evaluates scientific, clinical, and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases; the quality characteristics which such drugs purport or are represented to have, and as required, any other product for which the Food and Drug Administration has regulatory responsibility; and makes appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

The Committee shall consist of a core of 14 voting members including two Chairpersons. Members and Chairpersons are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical sciences (pharmaceutical manufacturing, bioequivalence research, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, molecular biology, immunology, microbiology); clinical pharmacology (dose-response, pharmacokinetics-pharmacodynamics, modeling and simulation, pharmacogenomics, clinical trial design, pediatrics and special populations and innovative methods in drug development); biostatistics, related biomedical and pharmacological specialties, current good manufacturing

practices, and quality systems implementation. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include up to three non-voting members who are identified with industry interests.

Further information regarding the most recent charter and other information can be found at: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AdvisoryCommitteeForPharmaceuticalScienceandClinicalPharmacology/ucm107524.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). Due to a change in the committee name, FDA will publish a final rule will in the **Federal Register** amending 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: January 15, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Programs.

[FR Doc. 2016-01181 Filed 1-21-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60 Day Information Collection: Indian Health Service Forms To Implement the Privacy Rule

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, "IHS Forms to Implement the Privacy Rule (45 CFR parts 160 and 164)," Office of Management and Budget (OMB) Control Number 0917-0030.

DATES: *Comment Due Date:* March 22, 2016. Your comments regarding this

information collection are best assured of having full effect if received within 60 days of the date of this publication.

ADDRESSES: Send your written comments, requests for more information on the collection, or requests to obtain a copy of the data collection instrument and instructions to Tamara Clay by one of the following methods:

- *Mail:* Tamara Clay, Information Collection Clearance Officer, Indian Health Service, Office of Management Services, Division of Regulatory Affairs, 5600 Fishers Lane, Mail Stop 09E70, Rockville, MD 20857.
- *Phone:* 301-443-4750.
- *Email:* tamara.clay@ihs.gov.
- *Fax:* 301-443-2316.

SUPPLEMENTARY INFORMATION: This previously approved information collection project was last published in the **Federal Register** (78 FR 2412) on January 11, 2013, and allowed 30 days for public comment. No public comment was received in response to the notice. This notice announces our intent to submit the collection, which expires April 30, 2016, to OMB for approval of an extension, and to solicit comments on specific aspects of the information collection. A copy of the supporting statement is available at www.regulations.gov (see Docket ID IHS-2016-1).

Title of Collection: 0917-0030, IHS Forms to Implement the Privacy Rule (45 CFR parts 160 and 164). *Type of Information Collection Request:* Extension of the currently approved information collection, 0917-0030, IHS Forms to Implement the Privacy Rule (45 CFR parts 160 and 164). *Form(s):* IHS-810, IHS-912-1, IHS-912-2, IHS-913, and IHS-917. *Need and Use of Information Collection:* This collection of information is made necessary by the Department of Health and Human Services Rule entitled "Standards for Privacy of Individually Identifiable Health Information" (Privacy Rule) (45 CFR parts 160 and 164). The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996, creates national standards to protect individual's personal health information, and gives patients increased access to their medical records. 45 CFR 164.508, 164.522, 164.526 and 164.528 of the Rule require the collection of information to implement these protection standards and access requirements. The IHS will continue to use the following data collection instruments to meet the