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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This draft guidance refers to previously approved collections of information found in FDA regulations.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The Agency invites comments on the “Postmarket Management of Cybersecurity in Medical Devices” draft guidance, in general, and on the following questions, in particular: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- In the draft guidance, the FDA is proposing its intention to not enforce certain regulatory requirements for manufacturer’s that are “participating members” of an ISAO.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]

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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