considerations for including patient preference information in labeling for patients and health care professionals. This draft guidance includes examples that illustrate how patient preference information may inform FDA's regulatory decisionmaking. The guidance applies to both diagnostic and therapeutic devices that are subject to these review processes. Additionally, this guidance may apply to other stakeholders such as patient groups and academia who may wish to conduct patient preference studies.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Patient Preference Information—Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Device Labeling. 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.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Patient Preference Information—Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Device Labeling'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500006 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to currently 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 812.25(c) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 subparts B and E have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814 subpart H have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Specifically the Agency would like comments on the following questions:

1. Section IV of the draft guidance recommends qualities for patient preference studies. Do you believe these recommended qualities are clear and understandable? If not, what should be reworded or edited? Is there anything missing? If so, what needs to be added?

2. Under what conditions should health care professional or patient labeling include information about patient preference studies?

3. How should sponsors present patient preference information in the health care professional and patient labeling?

4. How should labeling indicate that only a subset of patients in a patient preference study were willing to accept certain risks in order to achieve probable benefits?

5. How should sponsors and the FDA ensure that patients receive and understand patient preference information?

Dated: May 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11819 Filed 5–15–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0545]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Infant Formula Requirements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 4, 2015, the Agency submitted a proposed collection of information entitled, ''Infant Formula Requirements'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0256. The approval expires on April 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11821 Filed 5–15–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings.

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections