obligation to obtain an IND for the following types of studies evaluating the effects of a product marketed as a conventional food or dietary supplement:

For conventional foods:

• Clinical studies designed to evaluate whether a conventional food may reduce the risk of a disease, intended to support a new or expanded health claim, and conducted in a population that does not include individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions;

• Clinical studies designed to evaluate a non-nutritional effect of a conventional food on the structure or function of the body.

For dietary supplements:

• Clinical studies designed to evaluate whether a dietary supplement may reduce the risk of a disease, intended to support a new or expanded health claim, and conducted in a population that does not include individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions.

Further, as noted in the final guidance itself, no IND is required for clinical studies designed to evaluate the nutritional effects of a conventional food, clinical studies designed to evaluate a dietary supplement's effects on the structure or function of the body, or clinical studies designed to evaluate the relationship between a conventional food or dietary supplement and reduced risk of a disease, if there is already an authorized health claim for the substance-disease relationship.

The following types of studies do continue to require an IND for the reasons explained in the final guidance:

For conventional foods:

• Clinical studies designed to evaluate a conventional food's ability to diagnose, cure, mitigate, treat, or prevent a disease, except for studies designed to evaluate whether a conventional food reduces the risk of a disease, intended to support a health claim, and conducted in a population that does not include individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions;

• Clinical studies designed to evaluate whether a food substance reduces the risk of a disease, intended to support a new or expanded health claim, and conducted in a population that includes individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions.

For dietary supplements:

• Clinical studies designed to evaluate a dietary supplement's ability to diagnose, cure, mitigate, treat, or prevent a disease, except for studies designed to evaluate whether a dietary supplement reduces the risk of a disease, intended to support a health claim, and conducted in a population that does not include individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions;

• Clinical studies designed to evaluate whether a dietary supplement reduces the risk of a disease, intended to support a new or expanded health claim, and conducted in a population that includes individuals less than 12 months old, those with altered immune systems, or those with serious or life-threatening medical conditions.

For cosmetics:

• Clinical studies designed to evaluate a cosmetic's effect on the structure or function of the body or its ability to diagnose, cure, mitigate, treat, or prevent a disease.

Dated: October 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27729 Filed 10–29–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3805]

Clinical Trials—Assessing Safety and Efficacy for Diverse Populations; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the Johns Hopkins Center of Excellence in Regulatory Science and Innovation, is announcing a public workshop entitled ''Clinical Trials—Assessing Safety and Efficacy in Diverse Populations.'' The purpose of the meeting is to discuss approaches in clinical trial design and subgroup analyses for therapeutic product development and life-cycle management.

DATES: The meeting will be held on December 2, 2015, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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–2015–N–3805 for Clinical Trials—Assessing Safety and Efficacy for Diverse Populations; Public Meeting; Request for Comments. Received

comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://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 *http://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 *http://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: Martin Mendoza, Office of Minority Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2306, Silver Spring, MD 20993–0002, *Martin.Mendoza@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this public workshop is to facilitate a unique opportunity for relevant stakeholders, including industry, academia, patients, and FDA, to discuss the importance of diversity in medical research and the incorporation of participant diversity in the design, analysis, and regulation of medical interventions. Medical interventions may have different benefits and harms for subgroups within a population. If clinical trials do not include an adequate number of participants who are representative of people likely to use an approved intervention, then the average results of clinical trials might not be replicated in practice. Even if clinical trials include representative participants, important subgroup differences might not be detectable if their representation is not adequate. For these reasons, regulators might use a combination of information from clinical trials and other data sources to address questions about heterogeneity across large and diverse populations. The use of data from patients in their usual care setting (''real-world'' data) may be particularly valuable for understanding this heterogeneity.

Agenda: The agenda is located at: *http://www.jhsph.edu/research/centers-and-institutes/center-of-excellence-in-regulatory-science-and-innovation/news-and-events/clinical-trials-assessing-safety-and-efficacy-for-diverse-population.html.* (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**).

Registration: There is no registration fee to attend this meeting. Seats are limited, and registration will be on a first-come, first-served basis. To register, please complete registration online at *http://www.surveymonkey.com/r/ClinicalTrialsWorkshop120215.* (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Accommodations: Attendees are responsible for their own hotel accommodations. If you need special accommodations due to a disability, please contact Jill Zung at *Jill.Zung@fda.hhs.gov* at least 7 days in advance.

Dated: October 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27728 Filed 10–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1167]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Controlled Correspondence Related to Generic Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Controlled Correspondence Related to Generic Drug Development'' 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 July 9, 2015, the Agency submitted a proposed collection of information entitled ''Guidance for Industry on Controlled Correspondence Related to Generic Drug Development'' 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 0910–0797. The approval expires on September 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: October 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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