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Dated: October 20, 2016.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

Dated: October 20, 2016.

Lillian Sparks Robinson,

Commissioner, Administration for Native Americans.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2817]

Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment.” The purpose of this guidance is to assist sponsors in developing drugs for the treatment of low sexual interest, desire, and/or arousal in women. Specifically, this guidance addresses FDA’s current thinking regarding the overall clinical development program, with a focus on phase 3 trial designs, to support an indication for the treatment of these conditions.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 27, 2016.

ADDRESSES: 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-2016-D-2817 for Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment; Draft Guidance for Industry; Availability. 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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jennifer Mercier, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5390, Silver Spring, MD 20993-0002, 301-796-0957.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs

for Treatment.” The purpose of this draft guidance is to assist sponsors in developing drugs for the treatment of low sexual interest, desire, and/or arousal in women. Specifically, this draft guidance addresses FDA’s current thinking regarding the overall clinical development program, with a focus on phase 3 trial designs, to support an indication for the treatment of these conditions.

On October 27, 2014, FDA convened a public patient-focused drug development meeting and heard directly from women suffering from female sexual desire and arousal disorders. The following day, FDA held a public scientific workshop with invited experts in sexual medicine to discuss scientific challenges involved in developing drugs to treat these disorders, including diagnostic criteria, endpoints, and patient-reported outcome instruments. Comments from the public and experts that were communicated during these proceedings, as well as comments submitted to FDA through the public docket, were used to inform this draft 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 developing drugs for the treatment of low sexual interest, desire, and/or arousal in women. 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.

II. The 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 314 have been approved under OMB Control Number 0910–0001.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: October 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0823]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by November 25, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0340. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Format and Content Requirements for OTC Drug Product Labeling—21 CFR Part 201—OMB Control Number 0910–0340—Extension

In the *Federal Register* of March 17, 1999 (64 FR 13254) (the 1999 labeling final rule), we amended our regulations governing requirements for human drug

products to establish standardized format and content requirements for the labeling of all marketed OTC drug products in part 201 (21 CFR part 201). The regulations in part 201 require OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. Specifically, the 1999 labeling final rule added new § 201.66 to part 201. Section 201.66 sets content and format requirements for the Drug Facts portion of labels on OTC drug products.

On June 20, 2000 (65 FR 38191), we published a *Federal Register* final rule that required all OTC drug products marketed under the OTC monograph system to comply with the labeling requirements in § 201.66 by May 16, 2005, or sooner (65 FR 38191 at 38193). Currently marketed OTC drug products are already required to be in compliance with these labeling requirements, and thus will incur no further burden to comply with Drug Facts labeling requirements in § 201.66. Modifications of labeling already required to be in Drug Facts format are usual and customary as part of routine redesign practice, and thus do not create additional burden within the meaning of the PRA. Therefore, the burden to comply with the labeling requirements in § 201.66 is a one-time burden applicable only to new OTC drug products introduced to the marketplace under new drug applications (NDAs), abbreviated new drug applications (ANDAs), or an OTC drug monograph, except for products in “convenience size” packages.¹ New OTC drug products must comply with the labeling requirements in § 201.66 as they are introduced to the marketplace.

Based on a March 1, 2010, estimate provided by the Consumer Healthcare Products Association (75 FR 49495 at 49496, August 13, 2010), we estimated that approximately 900 new OTC drug product stock-keeping units (SKUs) are introduced to the marketplace each

¹ In a final rule published in the *Federal Register* of April 5, 2002, the Agency delayed the compliance dates for the 1999 labeling final rule for all OTC drug products that: (1) Contain no more than two doses of an OTC drug and (2) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear labeling to meet the requirements set forth in § 201.66(d)(1) and (9) and, therefore, qualify for the labeling modifications currently set forth in § 201.66(d)(10) (67 FR 16304 at 16306). The Agency issued this delay in order to develop additional rulemaking for these “convenience size” products (December 12, 2006; 71 FR 74474). These products are not currently subject to the requirements of § 201.66. PRA approval for any requirements to which they may be subject in the future will be handled in a separate rulemaking.