4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0817]

Draft Guidance for Industry and Food and Drug Administration Staff; Evaluation of Sex Differences in Medical Device Clinical Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Evaluation of Sex Differences in Medical Device Clinical Studies." This document provides guidance on the study and evaluation of sex differences in medical device clinical trials, with a specific focus on addressing potential differences in study design, conduct, outcomes, and interpretation that should be considered to ensure sex-specific issues are adequately addressed in clinical trials. This draft guidance is not final nor is it in effect at this time.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Evaluation of Sex Differences in Medical Device Clinical Studies" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological

Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this guidance is to outline the Center for Devices and Radiological Health's (CDRH's) expectations regarding sex-specific patient enrollment, data analysis, and reporting of study information. The intent is to improve the quality and consistency of available data regarding the performance of medical devices in women. This information can be of benefit to patients and their medical providers, as well as clinical researchers and others. The specific

objectives of this guidance are to: (1) Better communicate the balance of risks and benefits of FDA-approved or cleared medical devices; (2) identify sex-specific questions for further study; and (3) encourage the consideration of sex and associated covariates (e.g., body size, plaque morphology, etc.) during the trial design stage.

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 Agency's current thinking on "Evaluation of Sex Differences in Medical Device Clinical Studies." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. To receive "Evaluation of Sex Differences in Medical Device Clinical Studies," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1727 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910-0449.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: December 13, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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