



This document is scheduled to be published in the Federal Register on 08/22/2014 and available online at <http://federalregister.gov/a/2014-19939>, and on FDsys.gov

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Evaluation of Sex-Specific Data in Medical Device Clinical Studies; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Evaluation of Sex-Specific Data in Medical Device Clinical Studies.” This document provides guidance on the study and evaluation of sex-specific data in medical device clinical studies, and it outlines the Center for Devices and Radiological Health’s (CDRH’s) and Center for Biologics Evaluation and Research’s (CBER’s) expectations regarding sex-specific patient enrollment, data analysis, and reporting of device study information. The guidance is intended to improve the quality and consistency of available data regarding the performance of medical devices in both sexes by encouraging appropriate enrollment by sex in clinical studies of devices, and appropriate interpretation and assessment if data from such studies are analyzed by sex. Evaluation of sex-specific data in medical device clinical studies can benefit patients, their medical providers, clinical researchers, and others.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic

access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Evaluation of Sex-Specific Data in Medical Device Clinical Studies” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the 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: Jismi Johnson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1524, Silver Spring, MD 20993-0002, 301-796-6424; or Kathryn O’Callaghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3614, Silver Spring, MD 20993-0002, 301-796-6349; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this guidance is to outline CDRH’s and CBER’s expectations regarding sex-specific patient enrollment, data analysis, and reporting of medical device study information.

The intent is to improve the quality and consistency of available data regarding the performance of medical devices in both sexes by encouraging appropriate enrollment by sex in clinical studies of devices, and appropriate interpretation and assessment when data from such studies are analyzed by sex. This information can benefit patients, their medical providers, clinical researchers, and others. The specific objectives of this guidance are to: (1) Encourage the consideration of sex and associated covariates (e.g., body size, plaque morphology, etc.) during the study design stage; (2) provide recommendations for study design and conduct to encourage appropriate enrollment of each sex (e.g., in proportions generally representative of the demographics of disease distribution, if appropriate); (3) outline recommended sex-specific statistical analyses of study data with a framework for considering sex-specific data when interpreting overall study outcomes; and (4) specify FDA's expectations for reporting sex-specific information in summaries and labeling for approved or cleared medical devices.

In the Federal Register of December 19, 2011 (76 FR 78670), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by March 19, 2012. Multiple comments were received with recommendations pertaining to the evaluation of sex-specific data in clinical studies. In response to these comments, FDA revised the guidance document to clarify the processes of sex-specific data evaluation in clinical studies and policies as appropriate. For more clarity, a decision framework for different clinical study designs was added to the guidance in response to comments received requesting additional information on when various sex-specific statistical recommendations would apply. Additionally, several comments requested that the recommendations in the guidance apply to the demographic subgroups of age, race, and ethnicity. However, this is outside of the scope of the

revised guidance but, where applicable, the guidance was updated with links to other guidances and information related to these other demographic subgroups.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on evaluation of sex-specific data 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 guidance may do so by downloading an electronic copy from 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> or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. Persons unable to download an electronic copy of "Evaluation of Sex-Specific Data in Medical Device Clinical Studies," may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1727 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 822 have been approved under OMB control number 0910-0449.

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>.

Dated: August 19, 2014.

Peter Lurie,
Associate Commissioner for Policy and Planning.