Exhibit A-17

GUIDANCE DOCUMENT

Study of Sex Differences in the Clinical Evaluation of Medical Products

JANUARY 2025

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Draft

Not for implementation. Contains non-binding recommendations.

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Docket Number:

FDA-2024-D-4245

Issued by:

Center for Biologics Evaluation and Research
Center for Devices and Radiological Health
Center for Drug Evaluation and Research

Per a court order, HHS is required to restore this website as of 11:59 PM on February 11, 2025. Any information on this page promoting gender ideology is extremely inaccurate and disconnected from the immutable biological reality that there are two sexes, male and female. The Trump Administration rejects gender ideology and condemns the harms it causes to children, by promoting their chemical and surgical mutilation, and to women, by depriving them of their dignity, safety, well-being, and opportunities. This page does not reflect biological reality and therefore the Administration and this Department reject it.

This guidance provides recommendations for increasing enrollment of females in clinical trials, analyzing and interpreting sex-specific data, and including sex-specific information in regulatory submissions of medical products. Clinical trials and non-interventional studies of medical products should be designed to enroll sufficient numbers of females and males to reflect the prevalence of the disease or condition for which the medical product is being investigated to help ensure the generalizability of results and facilitate exploration of potential differences in effects by sex. When finalized, this guidance will replace the guidance entitled “Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs” issued in July 1993.

Content current as of:
01/07/2025

Regulated Product(s)
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