4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2776]

Evaluating Inclusion and Exclusion Criteria in Clinical Trials; Workshop Report; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency is announcing the availability of a summary report of a public workshop that was held on April 16, 2018, entitled "Evaluating Inclusion and Exclusion Criteria in Clinical Trials." The FDA Reauthorization Act of 2017 (FDARA) requires that the Agency convene a public workshop to discuss clinical trial eligibility criteria to inform a guidance on this subject and to publish a report summarizing the topics discussed within 90 days of the public workshop. This summary report fulfills FDA's mandate under FDARA.

ADDRESSES: For persons without internet access, copies of the summary report can be requested from the Division of Drug Information, Food and Drug Administration, by mail: 10001 New Hampshire Ave, Silver Spring, MD 20993-0002, or toll free telephone: 855-543-3784.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 51, Rm. 3326, Silver Spring, MD 20993, 301-796-2500, Dianne.Paraoan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 610 of FDARA requires that FDA convene a public workshop to discuss clinical trial eligibility criteria to inform a guidance on this subject and to publish a report summarizing the topics discussed within 90 days of the public workshop (Pub. L. 115-52). On April 16, 2018, FDA convened the public workshop required by FDARA entitled "Evaluating Inclusion and Exclusion Criteria in Clinical Trials." This notice announces the availability of the report required by FDARA that summarizes the major points explored with stakeholders during the public workshop. The report is intended only as a summary of the workshop discussions and does not provide guidance or reflect FDA's current thinking on this subject. The workshop report was posted on FDA's website on July 11, 2018.

II. Electronic Access

Persons may obtain the summary report at https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDARA/ucm598050.htm.

Dated: August 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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