4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0812]

Electronic Study Data Submission; Data Standard Support; Availability of the Center for Drug Evaluation and Research Data Standards Program Documents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) is announcing the availability of the CDER Data Standards Strategy (version 1.0) and the CDER Data Standards Strategy--Action Plan (version 1.0). This action is being taken to ensure that all interested stakeholders are aware that the data standards program documents are available and is intended to increase awareness of CDER's data standards plans, ongoing projects, and avenues of communication. Comments may be submitted to the email address listed below.

FOR FURTHER INFORMATION CONTACT: Office of Strategic Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1100, Silver Spring, MD 20993, 301-796-3800; email: CDERDataStandards@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

On December 5, 2012, the CDER Data Standards Strategy (version 1.0) was released. Its purpose is to reinforce FDA's ongoing commitment to the development, implementation, and maintenance of a comprehensive data standards program to facilitate the efficient and effective review of regulatory submissions so that safe and effective products can get to market sooner. It

is aligned with the objectives of FDA's Strategic Plan and the performance goals of the Prescription Drug User Fee Act V Reauthorization as captured in the FDA Safety and Innovation Act. The CDER Data Standards Strategy supersedes version 1.1 of the CDER Data Standards Plan, which was issued in December 2010.

The first release of the companion document to the Data Standards Strategy, the CDER Data Standards Strategy--Action Plan, was issued on March 20, 2013. The Action Plan provides internal and external stakeholders with an overview and progress of current relevant data standards initiatives. The plan will be updated quarterly to indicate progress of current projects as well as initiation of new projects.

These documents are available from the CDER Data Standards Program Web site at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm249979.htm.

Dated: July 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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