4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1277]

AGENCY: Food and Drug Administration, HHS.

Therapeutic Area Standards Initiative Project Plan; Availability

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the Therapeutic Area Standards Initiative Project Plan. This therapeutic area (TA) Project Plan will be the primary document for guiding all major aspects of FDA's multi-year initiative to develop and implement TA standards to support the regulatory review process for drugs and biologics. The TA Project Plan will be updated annually and made available for public comment.

DATES: Although you can comment on this TA Project Plan at any time, to ensure that the Agency considers your comment on this TA Project Plan before it begins work on the next version of the TA Project Plan, submit either electronic or written comments on the TA Project Plan by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the TA Project Plan to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and Development (HFM-40). Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the TA Project Plan.

Submit electronic comments on the TA Project Plan 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.

FOR FURTHER INFORMATION CONTACT: Colleen Ratliffe, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1158, Silver Spring, MD 20993, email: CDERDataStandards@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the TA Project Plan. This TA Project Plan will be the primary document for guiding all major aspects of FDA's multi-year initiative to develop and implement TA standards to support the regulatory review process for drugs and biologics. Updated annually and made available for public comment, the plan will provide the overall management framework for addressing and accomplishing the PDUFA V objectives to develop and adopt clinical terminology standards for TAs.

Standardized data elements and terminologies enable data from multiple trials to be grouped for analysis, and meta-analyses within and across drug classes. In 2011, in response to an urgent need to further standardize study data terminologies and concepts

for efficacy analysis, FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) compiled a prioritized list of disease and TAs and made it available on FDA's Web site.[1] Several factors were considered in the identification and prioritization of these TAs: (1) Active investigational new drug applications (INDs), (2) existing standardization projects underway, and (3) industry input on drug development pipeline activity.

The Food and Drug Administration Safety and Innovation Act (FDASIA) reauthorized the Prescription Drug User Fee Act (PDUFA V) in July 2012. The PDUFA V Reauthorization Performance Goals and Procedures (Section XII)[2] states that FDA will prepare a project plan for developing distinct TA terminology standards, using a public process that allows for stakeholder input through open standards development organizations.

In November 2012, FDA requested public input relevant to study data standards by: (1) Convening a public meeting on November 5, 2012, entitled "Regulatory New Drug Review: Solutions for Study Data Exchange Standards" to receive input from stakeholders on the advantages and disadvantages of current and emerging alternatives for the exchange of regulated study data, and (2) issuing a notice in the August 14, 2012 Federal Register (77 FR 48491), informing the public of FDA's intent to prioritize and develop study data standards for identified TAs, and requesting public comment on the TA roadmap as well as recommendations on how the effort could be accomplished most efficiently. The TA Project Plan was developed based upon information from the

[1] http://www.fda.gov/TherapeuticAreaStandards.
[2] http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.

November 5, 2012, public meeting and public comments submitted in response to the November 20, 2012, Federal Register notice on the prioritization of TAs.

The TA standards should enable and enhance the ability to integrate, analyze, report, and share study data. As described in the TA Project Plan, CBER and CDER are actively collaborating with external stakeholders to support the development of these TA standards. Stakeholders are encouraged to engage in and support these data standardization efforts where possible, including providing feedback on the TA Project Plan.

II. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm or http://www.regulations.gov.

Dated: October 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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