4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0815]

Electronic Study Data Submission; Data Standards; Recommending the Use of the World Health Organization Drug Dictionary

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing support for the World Health Organization (WHO) Drug Dictionary (available at http://www.who-umc.org/), which is maintained and updated by the Uppsala Monitoring Centre. FDA is encouraging sponsors and applicants to use WHO Drug Dictionary codes in investigational study data provided in regulatory submissions to the Center for Drug Evaluation and Research and to the Center for Biologics Evaluation and Research. The WHO Drug Dictionary contains unique codes for identifying drug names and evaluating medicinal product information, including active ingredients and therapeutic uses. Typically, WHO Drug Dictionary is used to code concomitant medications used by subjects during the course of a clinical trial. WHO Drug Dictionary will be listed in the FDA Data Standards Catalog posted to FDA's Study Data Standards Resources Web site at http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm

DATES: Although you can comment on this notice at any time, to ensure that the Agency considers your comments submit either electronic or written comments by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 requests.

Submit electronic comments 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: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1192, Silver Spring, MD 20993-002, ronald.fitzmartin@fda.hhs.gov; 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, stephen.ripley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The use of a common dictionary to code concomitant medications is an important component of study data standardization. Generally, controlled terminology standards specify the key concepts that are represented as definitions, preferred terms, synonyms, codes, and code

system. The analysis of study data is greatly facilitated by the use of controlled terms for clinical or scientific concepts that have standard, predefined meanings and representations. WHO Drug Dictionary contains unique codes as drug names and corresponding medicinal product information, including active ingredients and the Anatomical Therapeutic Chemical (ATC) classification system for the therapeutic uses. Typically, sponsors and applicants use WHO Drug Dictionary to code and analyze concomitant medications taken by subjects during the course of clinical trials.

Although use of WHO Drug Dictionary codes are not required at this time, FDA now supports and encourages the use of WHO Drug Dictionary coded concomitant medications used in clinical trials. For purposes of this notice, "supported" means the receiving Center has established processes and technology to support receiving, processing, reviewing, and archiving files in the specified standard.

FDA is now encouraging sponsors and applicants to provide WHO Drug Dictionary codes for concomitant medication data in investigational studies provided in regulatory submissions (e.g., investigational new drug applications, new drug applications, abbreviated new drug applications, and biologics license applications). The codes should include the drug product trade name where available, the active ingredient(s) and the ATC class.

II. Comments

Interested persons may submit either electronic comments to http://www.regulations.gov or written comments regarding this notice 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: March 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-07269 Filed: 3/30/2015 08:45 am; Publication Date: 3/31/2015]