DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012-N–0710]

Electronic Study Data Submission; Data Standard Support End Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH) are announcing the end of support for the 3.1.1. version of Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) Implementation Guide (SDTM IG 3.1.1.). SDTM IG 3.1.2, which has been available since October 2009, is the newer standard supported by FDA. Support for SDTM IG 3.1.1 will end on January 28, 2015.

FOR FURTHER INFORMATION CONTACT: Virginia Hussong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1161, Silver Spring, MD 20993, Phone: 301–796–1016, *EDATA@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA encourages sponsors to submit standardized study data using Agency-supported data standards (see *http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm*).[1] An Agency-supported data standard means that FDA has established processes and technology infrastructure to support the receipt, processing, review, and archiving of study data using the standard. As data standards evolve, FDA will periodically end support for old standards in favor of newer standards that are better suited to meet FDA data management and review needs. FDA maintains a catalog of the supported data standards for study data submissions at *http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM292505.xls*.

To facilitate the transition to newer standards, FDA is committed to providing a transition period of 24 months during which both older and newer standards are supported. FDA first began supporting SDTM IG 3.1.2 on October 30, 2009, over 2 years ago.

This notice establishes that CBER, CDER, and CDRH are ending support for SDTM IG 3.1.1. effective January 28, 2015. Effective immediately, submitters are strongly encouraged to use SDTM IG 3.1.2 instead. The support end date is the date past which study data using the standard may not be submitted, unless special arrangements have been made in advance with the Agency.

FDA recognizes the challenges associated with adopting a new standard, particularly because studies are often conducted and study data are standardized months to years before submission to the Agency. Submitters seeking a special arrangement to provide data using SDTM IG 3.1.1 beyond the established support end date should submit a waiver request. A waiver request process will be posted at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm249979.htm* for CDER and *http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm209137.htm* for CBER by November 1, 2012. The waiver process will be put into place to support the transition and allow for submission of clinical data in SDTM IG 3.1.1 format data in cases where SDTM IG 3.1.2 is otherwise not feasible and/or when such submission has been determined as having no negative impact to the review process.

Dated: January 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01641 Filed 1–25–13; 8:45 am]

BILLING CODE 4160–01–P

[1] Section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112–144), requires electronic submission of drug and biologic applications beginning no earlier than 24 months after issuance of a final guidance. The final guidance, to be issued under section 745A of the FD&C Act following public notice and opportunity for comment, will specify the format required for such electronic submissions. The action announced in this notice, although applicable to electronic submission of standardized study data, is not being taken under section 745A of the FD&C Act and is not intended to trigger the mandatory submission requirements under that section.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0082]

Guidance for Industry on Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling.'' This guidance is intended to assist the pharmaceutical industry and other investigators engaged in new drug development in evaluating how variations in the human genome, specifically DNA sequence variants, could affect a drug's pharmacokinetics (PK), pharmacodynamics (PD), efficacy, or safety. The guidance provides recommendations on when and how genomic principles should be considered and applied in early-phase clinical studies to address questions arising during drug development and regulatory review.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance 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 the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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: Issam Zineh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3178, Silver Spring, MD 20993–0002, 301–796–4756; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Clinical Pharmacogenomics: Premarket

Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling.'' This guidance should help sponsors, researchers, and other interested persons engaged in new drug development in evaluating how variations in the human genome, specifically DNA sequence variants, could affect a drug's pharmacokinetics, pharmacodynamics, efficacy, or safety. The guidance provides recommendations on when and how genomic principles should be considered and applied in early-phase clinical studies to address questions arising during drug development and regulatory review. The guidance does not address trial design or statistical analysis considerations for later-phase randomized controlled clinical trials that are intended to draw definitive conclusions about treatment effects in a genomic subgroup or codevelopment of a drug and in vitro diagnostic. Rather, the considerations here are more relevant for exploratory and observational studies intended to generate genomic hypotheses that may then be tested in confirmatory trials.

Drug development is commonly described in ''phases'' (21 CFR 312.21). The first two phases provide initial information about safety and efficacy, and ideally examine a broad range of doses, so that the larger, later adequate, and well-controlled trials (phase 3) that are needed to support marketing approval can be efficiently designed. Across the drug development continuum, genomic data may be used for several purposes, including: (1) Identifying the basis for PK outliers and intersubject variability in clinical response; (2) ruling out the role of polymorphic pathways as clinically significant contributors to variable PK, PD, efficacy, or safety; (3) estimating the magnitude of potential drug-drug interactions; (4) investigating the molecular or mechanistic basis for lack of efficacy or occurrence of adverse reactions; and (5) designing clinical trials to test for greater effects in specific subgroups (i.e., use in study enrichment strategies).

On February 18, 2011 (76 FR 9583), FDA issued a draft of this guidance to solicit comments from the public. After carefully reviewing received comments and in light of increased regulatory experience and the evolution of the science, FDA has revised the guidance. In addition to making clarifying changes, FDA added content to describe when pharmacogenomics (PGx) studies are warranted, including circumstances when full sample ascertainment is expected to evaluate a specific hypothesis. In addition, a number of topics were further elaborated, including targeted sample collection, sample retention, genotyping approaches, pooled analyses, dedicated prospective PGx studies, genetic substudies, and safety PGx.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on conducting pharmacogenomic studies in early-phase clinical studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB control numbers 0910–0014 and 0910–0572.

III. 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.*

IV. Electronic Access

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

Dated: January 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01638 Filed 1–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0128; Formerly Docket No. 2007D–0396]

Detecting and Evaluating Drug-Induced Liver Injury; What's Normal, What's Not, and What Should We Do About It?; Public Conference; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference entitled ''Detecting and Evaluating Drug-Induced Liver Injury; What's Normal, What's Not, and What Should We Do About It?'' This conference will be cosponsored with the Critical Path Institute (C-Path) and the Pharmaceutical Research and Manufacturers of America. Its purpose is to discuss, debate, and build consensus among stakeholders in the pharmaceutical industry, academia, health care providers, patient groups, and regulatory bodies on how best to detect and assess the severity, extent, and likelihood of drug causation of liver injury and dysfunction in people using drugs for any medical purpose.

DATES: The public conference will be held on March 20, 2013, from 8 a.m. to 6 p.m. and March 21, 2013, from 8 a.m. until 4 p.m.

ADDRESSES: The conference will take place at the Marriott Inn & Conference Center, University of Maryland University College, 3501 University Blvd., East Hyattsville, MD 20783.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4307, Silver Spring MD 20993–0002, 301–796–0518, *lana.pauls@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2009, FDA announced the availability of guidance for industry entitled ''Drug-Induced Liver Injury: Premarketing Clinical Evaluation'' (74 FR 38035; July 30, 2009). This guidance explained that drug-induced liver injury (DILI) was the most frequent cause of safety-related drug marketing withdrawals for the past 50 years and that hepatotoxicity has limited use of many drugs that have been approved and prevented the approval of others. It