Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On September 30, 2014, the Agency submitted a proposed collection of information entitled ''Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0623. The approval expires on November 30, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–00204 Filed 1–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0092]

Study Data Technical Conformance Guide and Data Standards Catalog; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Study Data Technical Conformance Guide, Version 2.0 (Guide), and an update to the Data Standards Catalog (Catalog). The Guide supplements the final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (eStudy Data guidance) and provides specifications and recommendations for, as well as general considerations on, submitting standardized study data using FDA-supported data standards specified in the Catalog. The Guide is intended to complement and promote interactions between sponsors and FDA review divisions.

DATES: Submit either electronic or written comments on these documents at any time.

ADDRESSES: Submit written requests for a copy of the Study Data Technical Conformance Guide and the Data Standards Catalog 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. Send one self-addressed adhesive label to assist that office in processing your requests.

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: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993–0002, 301–796–5333, *ronald.fitzmartin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of Version 2.0 of the Guide and an update to the Catalog. The Guide supplements the final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*), and provides technical recommendations to sponsors for the electronic submission of standardized animal and human study data and related information contained in certain submissions to new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologic license applications (BLAs), and investigational new drug applications (INDs). The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (which was added by section 1136 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144)) for standardized study data contained in NDA, ANDA, BLA, and IND submissions.

The Guide is intended to complement and promote interactions between sponsors and FDA review divisions. It is not intended to replace the need for sponsors to communicate directly with review divisions regarding data standards implementation approaches or issues.

The Guide is organized as follows:

Section 1: ''Introduction''—provides information on regulatory policy and guidance background, purpose, and document control.

Section 2: ''Planning and Providing Standardized Study Data''—recommends and provides details on preparing an overall study data standardization plan, a study data reviewer's guide, and an analysis data reviewer's guide.

Section 3: ''Exchange Format—Electronic Submissions''—presents the specifications, considerations, and recommendations for the file formats currently supported by FDA.

Section 4: ''Study Data Submission Format: Clinical and Nonclinical''—presents general considerations and specifications for sponsors using, for example, the following standards for the submission of study data: Study Data Tabulation Model (SDTM), Analysis Data Model (ADaM), and Standard for Exchange of Nonclinical Data (SEND).

Section 5: ''Therapeutic Area Standards''—presents supplemental considerations and specific recommendations when sponsors submit study data using FDA-supported therapeutic area standards.

Section 6: ''Terminology''—presents general considerations and specific recommendations when using controlled terminologies/vocabularies for clinical trial data.

Section 7: ''Electronic Submission Format''—provides specifications and recommendations on submitting study data using the electronic Common Technical Document format.

Section 8: ''Data Validation and Traceability''—provides general recommendations on conformance to standards, data validation rules, data traceability expectations, and legacy data conversion.

In the **Federal Register** of February 6, 2014 (79 FR 7201), FDA announced the availability of Version 1.0 of the Study Data Technical Conformance Guide. The comment period on the Guide ended on May 7, 2014. We reviewed all comments received and revised it accordingly. Updates to Version 2.0 include, but are not limited to:

Section 2: Added a subsection to include an Analysis Data Reviewer's Guide.

Section 3: Clarified dataset sizes, column lengths, special characters for variables, and datasets.

Section 4: Clarified general considerations and domain specifications for SDTM and ADaM.

Section 6: Clarified a number of subsections, including controlled terminology, medications, pharmacologic class, and indication, and added a World Health Organization Drug Dictionary.

Section 7: Clarified the electronic submission format and the folder structure for study datasets.

Section 8: Renamed the section ''Data Validation and Traceability'' from ''Data Fitness'' and clarified several of the subsections, including Traceability Issues and Legacy Data Conversion.

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 Guide and the Catalog at either *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm* or *http://www.regulations.gov*.

Dated: January 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–00206 Filed 1–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

[CBP Dec. No. 15–01]

Expansion of Global Entry Eligibility to Citizens of the Republic of Panama

AGENCY: U.S. Customs and Border Protection; Department of Homeland Security.

ACTION: General notice.

SUMMARY: U.S. Customs and Border Protection (CBP) has established the Global Entry international trusted traveler program at most major U.S. airports. Global Entry allows pre-approved, low-risk participants expedited entry into the United States using Global Entry kiosks located at designated airports. Currently, eligibility for participation in Global Entry is limited to U.S. citizens, U.S. nationals, U.S. lawful permanent residents, Mexican nationals, and certain eligible citizens of the Netherlands, the Republic of Korea, the Federal Republic of Germany, the State of Qatar, and the United Kingdom. Additionally, participants in the NEXUS trusted traveler program and certain participants in the Secure Electronic Network for Travelers Rapid Inspection (SENTRI) trusted traveler program are permitted to use the Global Entry kiosks as part of their membership in those programs.[1] This document announces that CBP is expanding eligibility for Global Entry to include citizens of the Republic of Panama. All of these individuals must otherwise satisfy the requirements for participation in the Global Entry program. Additionally, this document announces that U.S. citizens who participate in Global Entry or U.S. citizens who can utilize Global Entry kiosks as NEXUS or SENTRI participants have the option to apply for membership in Panama Global Pass, the Republic of Panama's trusted traveler program.

DATES: The expansion of eligibility to citizens of the Republic of Panama will occur on January 12, 2015. Applications will be accepted from citizens of the Republic of Panama beginning January 12, 2015.

FOR FURTHER INFORMATION CONTACT: Larry Panetta, Office of Field Operations, (202) 344–1253, *Larry.A.Panetta@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Global Entry Program

Global Entry is a voluntary program that allows for the expedited clearance of pre-approved, low-risk travelers arriving in the United States at Global Entry kiosks located at designated airports. CBP issued the final rule that promulgated the regulation to establish Global Entry as an ongoing voluntary regulatory program in the **Federal Register** (77 FR 5681) on February 6, 2012. The final rule contains a detailed description of the program, the eligibility criteria, the application and selection process, and the initial airport locations. *See* 8 CFR 235.12. Travelers who wish to participate in Global Entry must apply via the Global On-Line Enrollment System (GOES) Web site, *https://goes-app.cbp.dhs.gov,* and pay the applicable fee. Applications for Global Entry must be completed and submitted electronically.

Eligibility for participation in Global Entry is limited to U.S. citizens, U.S. nationals, U.S. lawful permanent residents, and certain nonimmigrant aliens from countries that have entered into arrangements with CBP regarding international trusted traveler programs. Specifically, the regulation provides that certain nonimmigrant aliens from countries that have entered into arrangements with CBP concerning international trusted traveler programs may be eligible to apply for participation in Global Entry after CBP announces the arrangement by publication of a notice in the **Federal Register**. The notice will include the country, the scope of eligibility of nonimmigrant aliens from that country (*e.g.,* whether only citizens of the foreign country or citizens and non-citizens are eligible) and other conditions that may apply based on the terms of the arrangement. *See* 8 CFR 235.12(b)(1)(ii). In the preamble of the Global Entry final rule, CBP recognized the existence of previous arrangements it had with Mexico and the Netherlands regarding the international trusted traveler programs and announced that Mexican nationals and certain citizens of the Netherlands were eligible to apply for the Global Entry program. It further specified that Mexican nationals and citizens of the Netherlands who were existing participants in the Global Entry pilot would be automatically enrolled in the ongoing Global Entry program. Additionally, in the preamble of the Global Entry final rule, CBP recognized that pursuant to a previous **Federal Register** notice,[2] participants in NEXUS and certain participants in SENTRI would still be allowed to use the Global Entry kiosks.

In a notice published in the **Federal Register** (78 FR 48706) on August 9, 2013, CBP expanded Global Entry eligibility to include citizens of the Republic of Korea who are participants in the Smart Entry System (SES), a trusted traveler program for pre-approved, low-risk travelers at designated airports in the Republic of Korea via the use of e-gates; a limited number of citizens of the Federal Republic of Germany who are participants in the Automated and Biometrics-Supported Border Controls (ABG) Plus, a trusted traveler program in the Federal Republic of Germany; a limited number of citizens of the State of Qatar; and a limited number of citizens of the United Kingdom who frequently travel to the United States.

This document announces the further expansion of the Global Entry trusted

[1] See the Utilization of Global Entry Kiosks by NEXUS and SENTRI Participants **Federal Register** notice, December 29, 2010 (75 FR 82202) for further information.

[2] See the Utilization of Global Entry Kiosks by NEXUS and SENTRI Participants **Federal Register** notice, December 29, 2010 (75 FR 82202) for further information.