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 *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: June 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13544 Filed 6–10–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0636]

Global Unique Device Identification Database; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Global Unique Device Identification Database (GUDID): Guidance for Industry''. FDA has updated sections of the document, ''Global Unique Device Identification (GUDID): Draft Guidance for Industry'' in order to finalize the sections with the most questions from GUDID submitters. The guidance includes information about how device labelers (in most instances, the device manufacturer) will interface with the GUDID by establishing GUDID accounts and beginning their initial submissions. Draft guidance sections on the device identifier (DI) module have not been finalized in this document and will be addressed in a future document.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Global Unique Device Identification Database (GUDID): Guidance for Industry'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Alternatively, you may submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Bldg. 71, Rm. 3128, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to the office that you are ordering from to assist in processing your request.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *For information concerning the guidance as it relates to devices regulated by CDRH:* Indira R. Konduri, UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3303, Silver Spring, MD 20993–0002, 301–796–5995, email: *udi@fda.hhs.gov.*

For information concerning the guidance as it relates to devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85, 121 Stat. 824) and section 614 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144, July 9, 2012) amended the Federal Food, Drug, and Cosmetic Act to add section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue regulations establishing a unique device identification (UDI) system for medical devices along with implementation timeframes for certain medical devices. The UDI system final rule was published on September 24, 2013 (78 FR 58785).

In developing the final rule, FDA solicited and considered input from a variety of stakeholders (e.g., manufacturers, global regulatory bodies, the clinical community, and patient advocates) to ensure that as many perspectives as possible were incorporated. The GUDID is a critical component of the UDI system. The UDI assigned to each device is a globally unique, yet unintelligent code identifying the device, and is composed of the static DI portion and the dynamic production identifier. The GUDID will house the DI, along with key descriptive or ''attribute'' information about the device, which is reported and updated to the GUDID by the device labeler. Being unique for each device, the DI component of the UDI can be effectively used by stakeholders to access the GUDID attribute information for that device.

Labelers are responsible for submitting information to the GUDID. This guidance provides general information to labelers that will enable them to obtain a GUDID account and begin initial submissions to the GUDID. A draft version of this document (the ''draft guidance'') was released on September 24, 2013 (78 FR 58545), with a 60-day comment period, which ended on November 25, 2013. More than 300 comments were received from 21 entities. To provide labelers with the most accurate information as soon as it is available, we are finalizing this document in two phases. The first part of the finalized guidance, which is now being made available, addresses sections of the draft guidance that received the most comments and questions. The remaining sections of the draft guidance, including sections on the DI module, will be finalized in one or more parts to be published at a later date.

Keyed to the sections of the draft guidance, the guidance document released today deals with the following topics and the related comments and questions received during the comment period ended on November 25, 2013: (The remaining sections will be finalized at a later time.)

2—Unique Device Identifier
3—Global Unique Device Identification Database
3.1. GUDID Key Concepts
3.1.1 GUDID Account
3.1.2.2 Global Medical Device Nomenclature
3.2 GUDID Modules
3.2.1 GUDID Web Interface
3.2.1.1 GUDID Account Management Module

4—GUDID Submission and 21 CFR 11 Requirements
Appendix D—GUDID Attributes Mapped to a Fictitious Medical Device Label
Glossary

We are making available on the Internet at the FDA/UDI Web site (*http://www.fda.gov/udi*) updated versions of two appendices of the draft guidance: The section formerly identified as ''Appendix B'', which summarizes the device attribute information that will populate the GUDID, renamed as ''GUDID Data Elements Reference Table''; and the section formerly identified as ''Appendix C'', which summarizes the UDI formats accepted by the issuing agencies that FDA has accredited to date, renamed as ''UDI Formats by FDA-Accredited Issuing Agency''. These two documents contain technical specifications only, and we therefore are not going to publish them as a part of guidance that describes the Agency's interpretation of or policy on a regulatory issue. For those without Internet access or who otherwise would like to receive a hard copy of the currently updated version of either of these documents, formerly published as Appendix B and Appendix C of the draft guidance, please call the Contact Person (see **FOR FURTHER INFORMATION CONTACT**) to request the document(s).

II. Significance of Guidance

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 about the GUDID. 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 for interfacing with the GUIDID may be used with prior FDA approval if such approach satisfies the technical requirements of the GUDID and the requirements of the applicable statute and regulations. If you wish to use an alternative approach for submitting a specific required data element, you may request FDA approval by email or writing to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, email: *udi@fda.hhs.gov* (Attention: UDI Regulatory Policy Support). If a labeler has a waiver from electronic submission of GUDID data under § 830.320(c) (21 CFR 830.320(c)), the labeler must send a letter containing all of the information otherwise required by this guidance, as well as any permitted ancillary information that the labeler wishes to submit, within the time permitted to: UDI Regulatory Policy Support at the address indicated in the previous sentence. (See § 830.320(c)(3).)

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Global Unique Device Identification Database (GUDID): Guidance for Industry'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1831 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information described in FDA regulations. These collections of information 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 collection of information in 21 CFR part 830 pertaining to GUDID labeler accounts and data submissions addressed in this guidance document has been approved under OMB control number 0910–0720.

V. 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.*

Dated: June 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13568 Filed 6–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0758]

Draft Guidance for Industry on Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices.'' This guidance describes FDA's current thinking on recommended practices for drug manufacturers and their representatives to follow when distributing to health care professionals or health care entities scientific or medical journal articles that discuss new risk information for approved prescription drugs for human use, including drugs licensed as biological products, and approved animal drugs. The recommendations in this draft guidance are intended to address issues specific to the distribution of new information about risks associated with a drug that further characterizes risks identified in the approved labeling.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 25, 2014. Submit written comments on the proposed collection of information by *August 11, 2014.*

ADDRESSES: Submit written requests for single copies of the draft 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; 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; or to Communications Staff (HFV–12), Center