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available on the Internet at the FDA/UDI Web site (*http://www.fda.gov/udi*) updated versions of two appendices of the draft guidance: The section formerly identified as ''Appendix B'', which summarizes the device attribute information that will populate the GUDID, renamed as ''GUDID Data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of the currently updated version of either of these documents, formerly published as Appendix B and Appendix C of the draft guidance, please call the Contact Person (see **FOR FURTHER INFORMATION CONTACT**) to request the document(s).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

for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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:

Regarding prescription drugs: Lauren Wedlake, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6328, Silver Spring, MD 20993–0002, 301–796–2500.

Regarding prescription biological products: 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.

Regarding animal drugs: Dorothy McAdams, Center for Veterinary Medicine (HFV–216), 7519 Standish Pl., Rockville, MD 20855, 240–453–6802.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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.'' In February 2014, FDA issued a draft guidance entitled ''Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices'' to clarify the Agency's position on manufacturer dissemination of scientific or medical publications—including scientific or medical journal articles, scientific or medical reference texts, and clinical practice guidelines—that include information on unapproved new uses of the manufacturer's products. Stakeholders have raised questions regarding the Agency's position on manufacturer dissemination of new scientific or medical information about safety information contained in the labeling for approved drugs. Because this concerns dissemination of new risk information related to approved uses of a drug, this issue is distinct from the dissemination of information on unapproved new uses of approved drugs. In response to those questions, the Agency is issuing this draft guidance to clarify and solicit public comments on the Agency's position on manufacturer dissemination of new risk information regarding lawfully marketed drugs for approved uses to health care professionals or health care entities.

FDA recognizes that the safety profile of a drug evolves throughout its lifecycle as the extent of exposure to the product increases and that it can be helpful for health care practitioners to receive significant new risk information about an approved product in a timely manner. FDA anticipates that the earliest distribution of new risk information will generally involve distribution of recently published studies, as opposed to textbooks or clinical practice guidelines. Accordingly, FDA is providing guidance for manufacturers that choose to distribute new risk information in the form of a reprint or digital copy of a published study.

FDA believes that recommendations specific to the distribution of risk information are needed for two reasons:

- In general, there are differences in the purpose, nature, and reliability of the evidence used to determine the effectiveness of a drug (e.g., to support a new intended use) and the evidence that is the basis for a product's risk assessment. Therefore, FDA believes guidance is needed to address the spectrum of data sources that could be appropriate for distribution to provide new risk information.
- New risk information may contradict or otherwise deviate from the risk information in the approved labeling, which may cause confusion or otherwise contribute to patient harm. If the new information is unreliable or presented without the appropriate context, it could influence prescribing decisions or patient monitoring in a manner that could harm patients. Therefore, FDA is proposing recommendations for study or analysis and distribution criteria to help ensure that new risk information that rebuts, mitigates, or refines risk information in approved labeling meets appropriate standards for reliability and is presented with appropriate disclosure of its limitations.

The guidance is being issued in draft to enable public comment on the proposed recommendations.

In light of emerging case law, in particular the case law involving the First and Fifth Amendments of the United States Constitution, FDA is currently engaged in a comprehensive review of its regulations and guidance documents in an effort to harmonize the fundamental public health interests underlying FDA's mission and statutory framework with interests in the dissemination of truthful and non-misleading information. This draft guidance on distribution of risk information about approved prescription drugs and biological products is a part of that effort. This draft guidance does not address medical devices. FDA also plans to issue, by the end of the calendar year, additional guidance that addresses manufacturer responses to unsolicited requests, distributing scientific and medical information on unapproved new uses, manufacturer discussions regarding scientific information more generally, and distribution of health care economic information to formulary committees and similar entities.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices.'' 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 requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document. This draft guidance also refers to previously approved collections of information found in FDA regulations.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the

information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Recommendations for Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products.

Description of Respondents: Respondents to this collection of information are manufacturers of approved prescription drugs for human use, including drugs licensed as biological products, and approved animal drugs, and their representatives (firms).

Burden Estimate: The draft guidance pertains to the distribution, by firms, of scientific and medical publications that discuss new risk information for approved prescription drugs for human use and approved animal drugs (including prescription, non-prescription, and Veterinary Feed Directive drugs) marketed in the United States. The draft guidance recommends that if firms choose to distribute scientific and medical publications reflecting new risk information, those publications should have certain characteristics and certain other information should be distributed with them. Accordingly, the guidance recommends a ''third-party disclosure'' that constitutes a ''collection of information'' under the PRA.

If firms choose to distribute new risk information that rebuts, mitigates, or refines risk information in the approved labeling, and the information is in the form of a reprint or digital copy of a published study, the guidance provides recommendations regarding the characteristics of those publications. Specifically, with respect to the data source:

- The study or analysis should meet accepted design and other methodologic standards for the type of study or analysis (e.g., provides a clear description of the hypothesis tested, acknowledges and accounts for potential bias and multiplicity) and should be sufficiently well-designed and informative to merit consideration in assessing the implications of a risk.
- To rebut a prior determination (reflected in the approved labeling) that there is some basis to believe there is causal relationship between the drug and the occurrence of an adverse event, or to otherwise mitigate a described risk, the study or analysis should also be at least as persuasive as the data sources that underlie the existing risk assessment of causality, severity, and/or incidence of the adverse reaction as reflected in approved labeling (e.g., data from a new controlled trial designed to estimate the relative risk of the event, a pharmacoepidemiologic study that is capable of reliably estimating the relative risk, or a rigorous meta-analysis of all relevant data from new and existing controlled trials).
- The conclusions of the study or analysis should give appropriate weight and consideration to, and should be a fair characterization of, all relevant information in the safety database, including contrary or otherwise inconsistent findings. There is a broad spectrum of potential data sources that can contribute in some way to characterization of a product's safety; new risk information should be considered in light of all relevant existing information and integrated with that data to the extent possible.
- The study or analysis should be published in an independent, peer-reviewed journal.

The draft guidance also makes recommendations with respect to the distribution of the reprint or digital copy, including the recommendation that a cover sheet accompany the reprint or digital copy that clearly and prominently discloses the following:

- The study design, critical findings, and significant methodologic or other limitations of the study or analysis that may limit the persuasiveness or scope of findings that rebut, mitigate, or refine risk information in the approved labeling. Limitations should be discussed in relation to the specific circumstances of the study and its conclusions about a risk.
- The information is not consistent with certain risk information in the approved labeling (should specifically identify the inconsistent information).
- FDA has not reviewed the data.
- Any financial interests or affiliations between the study author(s) and the firm.

The reprint or digital copy should be accompanied by the approved labeling for the product, and when distributed, should be separate from any promotional material. Any statements made by a representative of the firm to a recipient concerning the reprint should be consistent with its content and the information in the disclosure cover sheet.

Additionally, FDA notes in the draft guidance that the recommendations in the guidance do not change a firm's existing obligations to revise its approved labeling in accordance with 21 CFR 201.56(a)(2), 314.70, 514.8(c) and 601.12. As described in this section of the document, this recommendation refers to previously approved collections of information found in FDA regulations. FDA estimates that approximately 500 firms annually distribute scientific and medical publications that discuss new risk information for approved prescription drugs. FDA also estimates that each firm would include some or all of the additional information described previously when distributing annually a total of approximately 4,250 scientific or medical journal articles that discuss new risk information for approved prescription drugs. FDA estimates that it will take each firm approximately 16 hours to make the disclosures recommended in this draft guidance, which includes the time needed to determine whether the article complies with the guidance recommendation on the characteristics of the scientific and medical publications that companies distribute, to determine financial conflicts of interest, to prepare the disclosure statements, and to attach the product labeling.

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Draft guidance on distributing scientific and medical publications on risk information for approved prescription drugs and biological products—recommended practices	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Distribution of scientific and medical publications on risk information	500	8.5	4,250	16	68,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This draft guidance also refers to previously approved collections of information found in FDA regulations with respect to submitting supplements to approved applications. These collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3502). The collection of information in 21 CFR 201.56(a)(2) has been approved under OMB control number 0910–0572; in 21 CFR 314.70 has been approved under OMB control number 0910–0001; in 21 CFR 601.12 has been approved under OMB control number 0910–0338; and in 21 CFR 514.8(c) has been approved under OMB control number 0910–0032.

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

Dated: June 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13569 Filed 6–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: July 9, 2014, 8:30 a.m.–5:30 p.m., July 10, 2014, 8:30 a.m.–3:30 p.m.

Place: To be determined. (The most current information, including the agenda, will be posted at: *http://www.hrsa.gov/advisorycommittees/mchbadvisory/InfantMortality/index.html*).

Status: The meeting is open to the public with attendance limited to space availability.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department of Health and Human Services' programs that focus on reducing infant mortality and improving the health status of infants and pregnant women and factors affecting the continuum of care with respect to maternal and child health care. It includes outcomes following childbirth; strategies to coordinate myriad federal, state, local, and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start Program and *Healthy People 2020* infant mortality objectives.

Agenda: Topics that will be discussed include the following: Health Resources and Services Administration (HRSA) Update; MCHB Update; Healthy Start Program Update; Updates from Partnering Agencies and Organizations; and ACIM's recommendations for the HHS National Strategy to Address Infant Mortality, specifically Strategy 2: The continuum of high-quality, patient-centered care.

Proposed agenda items are subject to change as priorities dictate. Time will be provided for public comments limited to 5 minutes each. Comments are to be submitted in writing no later than 5 p.m. ET on July 1, 2014.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Michael C. Lu, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration, Room 18 W, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (301) 443–2170. Individuals who are submitting public comments or who have questions regarding the meeting and location should contact David S. de la Cruz, Ph.D., M.P.H., ACIM Designated Federal Official, Health Resources and Services Administration, Maternal and Child Health Bureau, Telephone: (301) 443–0543, email: *David.delaCruz@hrsa.hhs.gov.*

Dated: June 4, 2014.

Jackie Painter,

Deputy Director, Division of Policy and Information Coordination.

[FR Doc. 2014–13527 Filed 6–10–14; 8:45 am]

BILLING CODE

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2014–0154]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICRs) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of a revision to the following collection of information: 1625–0005, Application and Permit to Handle Hazardous Materials. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before August 11, 2014.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2014–0154] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT). To avoid duplicate submissions, please use only one of the following means:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251. To ensure your comments are received in a timely manner, mark the fax, to attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at