final version of the guidance, submit either electronic or written comments on the draft guidance by May 7, 2014.

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, 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, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1160, Silver Spring, MD 20993, *ronald.fitzmartin@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act.'' FDASIA (Pub. L. 112–144), signed by the President on July 9, 2012, amended the FD&C Act to add section 745A entitled ''Electronic Format for Submissions.'' Drug and biologic submissions are addressed in section 745A(a).

Section 745A(a)(1) of the FD&C Act describes the general scope of section 745A(a) and provides that submissions under new drug applications (NDAs), abbreviated new drug applications (ANDAs), biological license applications (BLAs), and investigational new drug applications (INDs) must be in electronic format specified in FDA guidance. Section 745A(a)(2) states that the guidance issued by FDA may provide a timetable for future standards and criteria for waivers and exemptions. Section 745A(a)(3) provides that submissions under section 561 are exempt from the requirements of section 745A(a).

This guidance describes the scope of section 745A(a), the waivers of and exemptions from the electronic submission requirements, and the process and timetable that FDA will use to implement the electronic submission requirements. As described in the guidance, FDA will develop individual guidances to specify the electronic formats for certain submissions under section 745A(a). Under section 745A(a)(1) of the FD&C Act, electronic submissions can be required no earlier than 24 months after a final guidance is issued. Therefore, no earlier than 24 months after issuance of the final version of an individual guidance specifying the format for certain submissions under section 745A(a), the Agency will begin requiring that the submissions under NDAs, ANDAs, BLAs, or INDs be submitted in the specified electronic format.

The required format(s) for specific submissions and corresponding timetable(s) for implementation will be specified in individual guidances. Once an individual guidance is finalized and the timetable for implementation described in that guidance has passed, the guidance is considered to have binding effect and the electronic format(s) specified in that guidance must be used for submissions under certain NDAs, ANDAs, BLAs, or INDs.

In section 745A(a) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the format for the electronic submissions required under this section. Accordingly, to the extent that this draft guidance provides such requirements under section 745A(a) of the FD&C Act, indicated by the use of the words ''must'' or ''required'', this document is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d). FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance because this draft guidance contains binding provisions. The draft guidance, when finalized, will represent the Agency's current thinking on providing regulatory submissions in electronic format, as required under section 745A(a) of the FD&C Act.

II. Paperwork Reduction Act of 1995

This draft guidance contains no collection of information. As discussed in the draft guidance, FDA intends to develop individual draft guidances to specify the electronic formats for certain submissions under section 745A(a). We will discuss any information collection subject to clearance by OMB under the Paperwork Reduction Act in each **Federal Register** notice announcing the availability of the individual draft guidances that specify the required electronic formats.

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/Guidances/default.htm*, or *http://www.regulations.gov.*

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02553 Filed 2–5–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0097]

Revised Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Standardized Study Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled ''Providing

Regulatory Submissions in Electronic Format—Standardized Study Data.'' The draft guidance announced in this notice is being issued in accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA), which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to require that certain submissions under the FD&C Act and Public Health Service Act (PHS Act) be submitted in electronic format, beginning no earlier than 24 months after issuance of final guidance on that topic. The draft guidance describes how FDA plans to implement the requirements for the electronic submission of standardized study data contained in certain submissions to new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) and is being issued for public comment. This document supersedes the guidance entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' that was issued in February 2012.

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 May 7, 2014. Submit either electronic or written comments concerning the collection of information by April 7, 2014.

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, 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, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

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: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1160, Silver Spring, MD 20993, *ronald.fitzmartin@fda.hhs.gov*; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDASIA (Pub. L. 112–144), signed by the President on July 9, 2012, amended the FD&C Act to add section 745A, entitled ''Electronic Format for Submissions.'' Section 745A(a)(1) of the FD&C Act requires that submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C 355(b), (i), or (j)), and submissions under sections 351(a) or (k) of the PHS Act (42 U.S.C. 262(a) or (k)), be submitted to FDA in electronic format no earlier than 24 months after FDA issues final guidance on that topic.

In accordance with section 745A(a)(1) of the FD&C Act, FDA is issuing this draft guidance, announcing its determination that the study data contained in the submission types identified in this draft guidance must be submitted electronically (except for submissions that are exempted), in a format that FDA can process, review, and archive. Currently, the Agency can process, review, and archive electronic submissions of study data that use the standards, formats, and terminologies specified in the Study Data Standards Catalog [1] posted to FDA's Study Data Standards Resources Web page.

This revised draft guidance on standardized study data will supersede the draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' that was issued in February 2012. When finalized, this guidance implements the electronic submission requirements of section 745A(a) of the FD&C Act by specifying the format for electronic submission of study data contained in NDA, ANDA, BLA, and IND submissions. After publication of the **Federal Register** notice of availability of the final guidance, all studies with a start date [2] 24 months after the **Federal Register** notice must use the appropriate FDA supported standards, formats, and terminologies specified in the Data Standards Catalog for NDA, ANDA, and certain BLA submissions. Study data contained in certain IND submissions must use the specified formats for electronic submission in studies with a start date 36 months after the **Federal Register** notice of availability.

In Section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to implement the statutory electronic submission requirements by specifying the format for such submissions in guidance. Because this draft guidance provides such requirements under section 745A(a) of the FD&C Act, indicated by the use of the words ''must'' or ''required'', it is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d).

II. Paperwork Reduction Act of 1995

The draft 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 draft guidance pertains to sponsors and applicants making regulatory submissions to FDA in electronic format for NDAs, ANDAs, BLAs, and INDs. The information collection discussed in the draft guidance is contained in our IND regulations (21 CFR part 312) and approved under OMB control number 0910–0014, our NDA regulations (including ANDAs) (21 CFR part 314) and approved under OMB control number 0910–0001, and our BLA regulations (21 CFR part 601) and approved under OMB control number 0910–0338.

Sponsors and applicants have been voluntarily submitting standardized study data in electronic format. Under FDASIA, sponsors and applicants will be required to make all of these submissions electronically in compliance with the specified standards, formats, and terminologies. These requirements will be phased in over 2- and 3-year periods after the issuance of the final guidance.

For many years sponsors and applicants have been submitting electronically using the electronic common technical document format and have included electronic study data in both legacy and standardized formats. For some sponsors and applicants there may be new costs, including capital costs or operating and maintenance costs, which would result from the requirements under FDASIA and the final guidance, because some sponsors and applicants would have to change from submissions that have included

[1] Available at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm*.

[2] For purposes of this guidance, the study start date is the earliest date of informed consent among any subject that enrolled in the study. For example, see Study Start Date in the SDTM Trial Summary Domain (TSPARMCD = SSTDTC), *http://www.cdisc.org*.

legacy (non-standard) study data to submissions in compliance with the final guidance. FDA estimates that for some sponsors and applicants the costs may be as follows:

- Data management (hardware/software): $350,000–$1,000,000
- Initial data management operations: $500,000–$1,000,000
- Training $100,000–$250,000

III. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this document 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/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.regulations.gov*.

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02555 Filed 2–5–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0091]

Draft Guidance for Industry on Analgesic Indications: Developing Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Analgesic Indications: Developing Drug and Biological Products.'' This guidance provides recommendations to sponsors on the development of prescription drugs for the management of acute and chronic pain, as well as the management of breakthrough pain. Specifically, this guidance focuses on drug development and trial design issues and chemistry, manufacturing, and controls concerns that are unique to the study of acute, chronic, and breakthrough pain and the labeling considerations for analgesic drugs.

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 April 7, 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. 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: Sharon Hertz, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3156, Silver Spring, MD 20993–0002, 301–796–2280.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Analgesic Indications: Developing Drug and Biological Products.'' Analgesic development involves important concepts that should be considered during drug development, such as the duration of drug exposure for the treatment of acute and chronic pain and the subjective nature of pain intensity measurement. It is important that the spectrum of clinical studies planned during analgesic development provide an adequate characterization of the clinical, pharmacological, and, when feasible, pharmacodynamic behavior of the drug. This draft guidance presents the types of indications FDA may be willing to approve at present for analgesic drugs. It also presents general trial design issues, appropriate endpoints, and important safety considerations. For example, the guidance discusses the importance of appropriate statistical considerations that take into account the amount of nonrandom missing data in analgesic drug trials.

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 the development of drug and biological products for analgesic indications. 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 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 were approved under OMB control numbers 0910–0001, 0910–0338, and 0910–0014.

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/default.htm* or *http://www.regulations.gov.*

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02557 Filed 2–5–14; 8:45 am]

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