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]

BILLING CODE 4160–01–P

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Draft Guidance for Industry on Analgesic Indications: Developing Drug and Biological Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Analgesic Indications: Developing Drug and Biological Products.''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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 7, 2014.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.*

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Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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