4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. FDA-2013-D-0447]

Draft Guidance for Industry on Charging for Investigational Drugs Under an Investigational New Drug Application--Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Charging for Investigational Drugs Under an IND--Qs & As." This guidance is intended to provide information for industry, researchers, and physicians on how FDA is implementing its regulation on charging for an investigational drug under an investigational new drug (IND) application. FDA has received a number of questions about how it is implementing the charging regulation. Therefore, FDA is providing this draft guidance in a question and answer format, addressing the most frequently asked questions and answers, including questions about charging for investigational drugs made available under expanded access programs.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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; or 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

For the Center for Drug Evaluation and Research:

Colleen L. Locicero,

Center for Drug Evaluation and Research,

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For the Center for Biologics Evaluation and Research:

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301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Charging for Investigational Drugs Under an IND--Qs & As." In 2009, FDA amended its regulation concerning charging for investigational new drugs under an IND (August 13, 2009; 74 FR 40872). The new regulation, which went into effect on October 13, 2009, removed paragraph (d) of § 312.7 (21 CFR 312.7) and replaced it with new § 312.8. The new regulation is intended to clarify the circumstances in which charging for an investigational drug in a clinical trial is appropriate, to set forth criteria for charging for an investigational drug for the three types of expanded access for treatment use described in subpart I of 21 CFR part 312, and to clarify what costs can be recovered for an investigational drug. Elsewhere in this issue of the Federal Register, FDA is announcing the availability of the draft guidance entitled "Expanded Access to Investigational Drugs for Treatment Use--Qs & As," which is intended to provide information about FDA's implementation of its expanded access regulations (21 CFR part 312, subpart I).

Since § 312.8 has been in effect, FDA has received numerous questions about how it is implementing the regulation and interpreting various provisions. Consistent with the goal of clarifying the requirements for charging for an investigational drug and the types of costs that can be recovered, FDA is providing a draft guidance in a question and answer format, addressing

the most frequently asked questions and answers about charging for investigational drug under an IND.

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 charging for an investigational drug under an IND. 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found 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 collections of information in §312.8 have been approved under OMB control number 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, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default,or http://www.regulations.gov.

Dated: May 3, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

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