request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: May 3, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–11007 Filed 5–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. FDA–2013–D–0446]

Draft Guidance for Industry on Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Expanded Access to Investigational Drugs for Treatment Use—Qs & As.'' This guidance is intended to provide information for industry, researchers, physicians, and patients about certain aspects of FDA's implementation of its regulations on expanded access to investigational drugs for treatment use. FDA has received a number of questions about implementation of its expanded access regulations. Therefore, FDA is providing this draft guidance in a question and answer format, addressing the most frequently asked questions.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 8, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4200, Silver Spring, MD 20993–0002, 301–796–2270.

For the Center for Biologics Evaluation and Research: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Expanded Access to Investigational Drugs for Treatment Use—Qs & As.'' FDA's expanded access regulations (21 CFR part 312, subpart I) went into effect on October 13, 2009 (74 FR 40900).

These regulations contain the requirements for the use of investigational new drugs or approved drugs where availability is limited by a risk evaluation and mitigation strategy (REMS), when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. Under these regulations, there are three categories of expanded access based on the size of the patient population to be treated: (1) Individual patient access, including for emergency use; (2) intermediate-size patient population access; and (3) larger population access under a treatment protocol or treatment investigational new drug application (IND). These regulations are intended to facilitate the availability of investigational new drugs, or approved drugs where availability is limited by a REMS, to patients with serious or immediately life-threatening diseases or conditions who lack other therapeutic options and may benefit from investigational therapies.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance entitled ''Charging for Investigational Drugs Under an IND—Qs & As,'' which is intended to provide information about FDA's implementation of its regulation on charging for investigational drugs under an investigational new drug applications, including investigational drugs made available under expanded access programs.

One of FDA's major goals in promulgating these expanded access regulations was to make expanded access a more transparent process by increasing awareness and knowledge of expanded access programs and the procedures for obtaining investigational drugs for treatment use. Since these expanded access regulations went into effect in 2009, FDA has received a number of questions concerning its implementation of the regulations. Consistent with the goal of making expanded access processes more transparent, FDA is providing this draft guidance to address frequently asked questions about how it is interpreting various provisions in the expanded access regulations, including questions about when it is appropriate to request access under each of the three access categories, the types and content of access submissions, IRB review of individual patient expanded access, and the onset and duration of access use.

Although FDA is inviting comment on the entire draft guidance (21 CFR 10.115(g)(1)(ii)(C)), FDA notes that it is particularly interested in receiving comments on question 10. Question 10 asks, ''Is Institutional Review Board (IRB) review and approval required for individual patient expanded access?'' In the draft guidance, FDA explains that under current regulations for all expanded access uses, including individual patient access uses, investigators are required to ensure that IRB review and approval is obtained consistent with 21 CFR part 56 (21 CFR 312.305(c)(4)). 21 CFR part 56 requires, among other things, that an IRB review the expanded access use at a convened meeting at which a majority of the IRB members are present (''full IRB review'') (21 CFR 56.108(c)). However, FDA is aware of concerns that this requirement for full IRB review may deter individual patient access to investigational drugs for treatment use. FDA has encouraged use of central IRBs for review of expanded access uses to address these concerns. However, other options may be needed. Therefore, FDA is particularly interested in receiving comments on this issue, including to what extent the requirement for full IRB review of individual patient expanded access is a deterrent to patient access,

whether FDA should consider alternatives to full IRB review of individual patient expanded access, and what alternative approaches may better facilitate access while providing appropriate ethical oversight.

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 expanded access to investigational drugs for treatment use. 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 §§ 312.305, 312.310, 312.315, and 312.320 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.

[FR Doc. 2013–11005 Filed 5–8–13; 8:45 am]

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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 July 8, 2013.

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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4200, Silver Spring, MD 20993–0002, 301–796–2270.

For the Center for Biologics Evaluation and Research:

Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 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