protocol amendment to an existing IND by the sponsor of the existing IND); and (3) expanded access for widespread treatment use through a treatment IND or treatment protocol (designed for use in larger patient populations). The regulations are intended to facilitate, when appropriate, the availability of investigational new drugs outside of a clinical investigation or approved drugs where availability is limited by a risk evaluation and mitigation strategy (REMS) to patients with serious or immediately life-threatening diseases or conditions who lack other therapeutic options.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance for industry entitled ''Charging for Investigational Drugs Under an IND—Questions and Answers,'' which provides information about the implementation of FDA's regulation on charging for investigational drugs under an IND, including investigational drugs made available for expanded access use. (FDA's guidance documents are available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*. FDA has verified the Web site addresses throughout this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

Additionally, in this issue of the **Federal Register**, FDA is announcing the availability of a guidance for industry entitled ''Individual Patient Expanded Access Applications: Form FDA 3926.'' The guidance describes Form FDA 3926 (Individual Patient Expanded Access—Investigational New Drug Application (IND)), which is available for licensed physicians to use for expanded access requests for individual patient INDs as a streamlined alternative to Form FDA 1571 (Investigational New Drug Application (IND)), and describes the process for submitting expanded access requests for individual patient expanded access INDs.

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

In the **Federal Register** of May 9, 2013 (78 FR 27115), FDA announced the availability of the draft guidance entitled ''Expanded Access to Investigational Drugs for Treatment Use—Questions & Answers.'' FDA received several comments on the draft guidance, and those comments were considered as the guidance was finalized. Based on public comments, in addition to editorial changes made primarily for clarification, the final guidance includes significant clarification on the types of expanded access and when each type should be used.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on expanded access to investigational drugs for treatment use. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 21 CFR part 312 have been approved under OMB control number 0910–0014, and the collection of information resulting from the submission of Form FDA 3926 has been approved under OMB control number 0910–0814.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: May 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–13165 Filed 6–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0447]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Charging for Investigational Drugs Under an IND—Questions and Answers.'' The guidance provides information for industry, researchers, physicians, institutional review boards (IRBs), and patients about the implementation of FDA's regulation on charging for investigational drugs under an investigational new drug application (IND) for the purpose of either clinical trials or expanded access for treatment use. FDA received a number of questions concerning its implementation of the charging regulation. FDA is providing guidance in a question and answer format to address the most frequently asked questions about charging for investigational drugs under an IND. This guidance finalizes the draft guidance issued in May 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or

anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–0447 for ''Charging for Investigational Drugs Under an IND—Questions and Answers; Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Ebla Ali Ibrahim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6302, Silver Spring, MD 20993, 301–796–3691; or 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Charging for Investigational Drugs Under an IND—Questions and Answers.'' In 2009, FDA amended the regulation concerning charging for investigational new drugs under an IND (74 FR 40872, August 13, 2009). The new regulation, which went into effect on October 13, 2009, removed paragraph (d) of § 312.7 (21 CFR 312.7(d)) and replaced it with new § 312.8. The guidance clarifies the circumstances in which charging for an investigational drug under an IND for the purpose of clinical trials is appropriate and also sets forth criteria for charging for an investigational drug for the three types of expanded access for treatment use described in 21 CFR part 312, subpart I, and clarifies what costs can be recovered for an investigational drug.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance for industry entitled ''Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers,'' which provides answers to questions concerning the implementation of FDA's regulations on expanded access to investigational drugs for treatment use (part 312, subpart I). (FDA's guidance documents are available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*. FDA has verified the Web site addresses throughout this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

Additionally, in this issue of the **Federal Register**, FDA is announcing the availability of a guidance for industry entitled ''Individual Patient Expanded Access Applications: Form FDA 3926.'' That guidance describes Form FDA 3926 (Individual Patient Expanded Access—Investigational New Drug Application (IND)), which is available for licensed physicians to use for expanded access requests for individual patient INDs as a streamlined alternative to Form FDA 1571 (IND), and describes the process for submitting expanded access requests for individual patient INDs.

Since § 312.8 has been in effect, FDA has received numerous questions about its implementation of the charging regulation. 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 guidance in a question and answer format, addressing the most frequently asked questions and answers about charging for an investigational drug under an IND.

In the **Federal Register** of May 9, 2013 (78 FR 27116), FDA announced the availability of the draft guidance entitled ''Charging for Investigational Drugs Under an IND—Qs & As.'' FDA received several comments on the draft guidance, and those comments were considered as the guidance was finalized. Based on public comments, in addition to editorial changes primarily

for clarification, the major changes made to the guidance include adding clarification about charging for certain administrative costs in individual patient expanded access INDs and protocols, and the timing for submitting a request to FDA to reauthorize charging.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on charging for investigational drugs under an IND. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 21 CFR 312.8 and 312.320 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov*.

Dated: May 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–13166 Filed 6–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1255]

E18 Genomic Sampling and Management of Genomic Data; International Council for Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled ''E18 Genomic Sampling and Management of Genomic Data.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance pertains to genomic sampling and to the management of genomic data in clinical studies. The focus of this draft guidance is on the general principles of collecting, processing, transporting, storing, and disposing of genomic samples or data. The technical aspects of genomic sampling and research are also discussed when appropriate, recognizing the rapidly evolving technological advances in these areas. The draft guidance is intended to provide harmonized principles of genomic sampling and of managing genomic data in clinical studies.

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 2, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1255 for ''E18 Genomic Sampling and Management of Genomic Data.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the