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


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–3166 Filed 6–2–16; 8:45 am]

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E18 Genomic Sampling and Management of Genomic Data; International Council for Harmonisation; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled “E18 Genomic Sampling and Management of Genomic Data.” The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance pertains to genomic sampling and to the management of genomic data in clinical studies. The focus of this draft guidance is on the general principles of collecting, processing, transporting, storing, and disposing of genomic samples or data.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 The draft guidance is intended to provide harmonized principles of genomic sampling and of managing genomic data in clinical studies.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 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
harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of the ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CDRH, FDA; and the Pharmaceutical Research and Manufacturers of America. The standing members of the ICH Association include Health Canada and Swissmedic. Any party eligible as a member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the members of the ICH Association.

The ICH Assembly includes representatives from each of the ICH members, as well as observers from the World Health Organization and Drug Regulatory Authorities and Regional Harmonization Initiatives from around the world.

In December 2015, the ICH Assembly endorsed the draft guidance entitled “E18 Genomic Sampling and Management of Genomic Data” and agreed that the guidance should be made available for public comment. The draft guidance is the product of the Efficacy Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

The draft guidance provides guidance on genomic sampling and management of genomic data from interventional and non-interventional clinical studies. The draft guidance addresses use of genomic samples and data irrespective of the timing of analyses and both pre-specified and non-pre-specified use. The focus is on the general principles of collecting, processing, transporting, storing and disposing of genomic samples or data, within the scope of an informed consent. The technical aspects of genomic sampling and research are also discussed when appropriate, recognizing the rapidly evolving technological advances in these areas.

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 current thinking of FDA on “E18 Genomic Sampling and Management of Genomic Data.” It does not establish 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. Electronic Access


Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2016–11368 Filed 6–2–16; 8:45 am]

BILLING CODE 4164–01–P