discussion here. Specifically, FDA received numerous comments regarding two categories of requests that FDA proposed in the draft guidance to exclude from the controlled correspondence process. First, FDA received comments requesting that the Agency refrain from excluding requests for product-specific guidance on demonstrating bioequivalence. FDA declines to revise the guidance in this fashion. As set out in the draft guidance, the short timeframe contemplated for the controlled correspondence responses is inconsistent with the well-established process for issuing product-specific recommendations described in the guidance for industry on ''Bioequivalence Recommendations for Specific Products (June 2010)'', as well as with the principles in the GDUFA Commitment Letter regarding the Regulatory Science Initiative. Rather than incorporating such guidance development into the controlled correspondence process, FDA's Office of Generic Drugs (OGD) is developing a separate process for product-specific guidance development.

This approach is being managed by the Division of Therapeutic Performance (DTP) within OGD's Office of Research and Standards, involves representatives from numerous divisions and offices within OGD, and provides for timely posting of product-specific recommendations to facilitate generic drug development. Requests for product-specific guidance development received through the general *Generic Drugs@fda.hhs.gov* email account are forwarded directly to DTP for consideration and tracking. Prioritization of guidance development is based on a variety of factors, including public health needs, industry demand for generic development, anticipated expiration of reference listed drug exclusivity, formulation features and predictability of in vivo performance, OGD experience with similar formulations or product types, and the feasibility of different approaches to demonstrate bioequivalence (*e.g.,* pharmacokinetic/pharmacodynamics studies, comparative clinical endpoint studies, and in vitro approaches). FDA anticipates that this targeted development approach will expedite the availability of product-specific guidances while supporting the important policies of transparency and maximizing benefit to the public health.

Second, FDA received comments regarding its proposed method of responding to requests related to issues for which the Agency has not yet determined a policy. Upon review of the comments, FDA is revising its recommendations related to such inquiries. As described in the guidance, if there is a better mechanism for a requestor to obtain comment from FDA on the subject of the request than through a controlled correspondence, the Agency will direct the requestor to such a mechanism, *e.g.,* a pre-abbreviated new drug application meeting request or the Regulatory Science Initiative. For requests for which the controlled correspondence pathway is the best mechanism, but that raise issues for which FDA has not determined appropriate policy, such requests will remain open until such policy decision is made.

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 controlled correspondence related to generic drug development. 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 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 collection of information has been approved under OMB control number 0910–0797.

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* or *http://www.regulations.gov*.

V. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov*. (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA Commitment Letter) for fiscal years 2013 through 2017, available at *http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf*.

Dated: September 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24621 Filed 9–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3327]

E6(R2) Good Clinical Practice; International Conference on Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled ''E6(R2) Good Clinical Practice.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance amends the guidance entitled ''E6 Good Clinical Practice: Consolidated Guidance'' (E6(R1)) to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting, and also updates standards regarding electronic records and essential documents. The draft guidance is intended to improve clinical trial quality and efficiency while maintaining human subject protection. FDA is making this draft guidance available for comment on the sections that are additions to ICH E6(R1) and marked as ''ADDENDUM.''

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 the sections of this draft guidance marked as

''ADDENDUM'' before it begins work on the final version of the guidance, submit either electronic or written comments on the ''ADDENDUM'' sections of the draft guidance by November 30, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. 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: *Regarding the guidance:* Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993–0002, 301–796–2500; 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.

Regarding the ICH: Michelle Limoli, Center for Drug Evaluation and Research, International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7208, Silver Spring, MD 20993–0002, 301–796–8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and North America. The eight ICH sponsors 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 CBER, FDA; the Pharmaceutical Research and Manufacturers of America; Health Canada; and Swissmedic. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization.

In June 2015, the ICH Steering Committee agreed that a draft guidance entitled ''Good Clinical Practice E6(R2)'' should be made available for public comment. The draft guidance is the product of the ICH E6 Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the ICH E6 Expert Working Group.

The draft guidance provides guidance on approaches to clinical trial design, conduct, oversight, recording, and reporting as well as updated standards regarding electronic records and essential documents. The additions to ICH E6(R1) are intended to encourage implementation of the described approaches and processes to improve clinical trial quality and efficiency while maintaining human subject protection. Evolutions in technology and risk management processes offer new opportunities to increase clinical trial efficiency, in part by focusing on trial activities essential to ensuring human subject protection and the reliability of trial results. For example, the draft guidance recommends sponsors implement a system to manage quality throughout clinical trials and recommends sponsors develop a systematic, prioritized, risk-based approach to monitoring clinical trials. The draft guidance provides additional detail regarding recommendations for use of electronic trial data handling and remote electronic trial data systems.

This draft guidance includes additions to ICH E6(R1) that are identified as ''ADDENDUM'' and are marked with vertical lines on both sides of the text. FDA is making the draft guidance available for comment on the ''ADDENDUM'' text added to ICH E6(R1).

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 E6(R2) Good Clinical Practice. 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. 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.*

III. Electronic Access

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

Dated: September 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24623 Filed 9–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Intent To Grant Start-Up Exclusive Patent License: Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Antiviral Drugs

AGENCY: Public Health Service, HHS.