I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers.'' Because of increases in the number and complexity of ANDAs and FDA's desire to standardize generic drug review, on September 25, 2012 (77 FR 58999), FDA published a draft and on June 20, 2013 (78 FR 37231), published a final guidance recommending the generic industry follow the approach in the ICH stability-related guidances: (1) ''Q1A(R2) Stability Testing of New Drug Substances and Products,'' November 2003; (2) ''Q1B Photostability Testing of New Drug Substances and Products,'' November 1996; (3) ''Q1C Stability Testing for New Dosage Forms,'' November 1996; (4) ''Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products,'' January 2003; and (5) ''Q1E Evaluation of Stability Data,'' June 2004. These guidances can be found on the FDA Guidances (Drugs) Web site under International Conference on Harmonisation—Quality at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/ucm065005.htm.* FDA also recommended that industry follow the ICH outlined definitions, glossaries, references, and attachments.

While carefully considering the public comments on the September 2012 draft guidance, we decided to publish a draft guidance in a questions-and-answers format. This draft guidance discusses stability testing relating to general questions, drug master files, drug product manufacturing and packaging, amendments to pending ANDA applications, and stability studies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers. 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. 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. The 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 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

IV. Electronic Access

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

Dated: August 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20893 Filed 8–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0847]

Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Institutional Review Board Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an Investigational New Drug/Investigational Device Exemption is Needed; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed.'' The guidance announced in this notice is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in fulfilling responsibilities related to reviewing the qualifications of investigators and adequacy of research sites, and determining whether an investigational new drug (IND) application or investigational device exemption (IDE) is required, to protect the rights and welfare of human subjects involved in biomedical research.

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

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, 1–888–463–6332 or 301–796–3400; or the 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, 1–800–835–4709 or 301–827–1800; or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 4621, Silver Spring, MD 20993, 1–800–638–2041 or 301–796–7100. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Doreen Kezer, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5170, Silver Spring, MD 20993–0002, 301–796–8340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the

Determination of Whether an IND/IDE is Needed.'' This guidance is intended to assist IRBs, clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in determining that the proposed research satisfies the criteria for approval contained in 21 CFR 56.111, that ''[r]isks to subjects are minimized . . . [and] reasonable in relation to anticipated benefits, if any, to subjects . . .'' In particular, the guidance addresses the IRB's role in reviewing: (1) The qualifications of clinical investigators, (2) the adequacy of the research site, and (3) the determination of whether an IND/IDE is required.

Many of the recommendations in this guidance have appeared in other FDA guidance documents. FDA has compiled the recommendations from these various sources into this guidance to ensure that all IRBs have access to it. The guidance also explains how IRBs may efficiently fulfill these important responsibilities.

To enhance protection of human subjects and reduce regulatory burden, the Department of Health and Human Services, Office for Human Research Protections (OHRP), and FDA have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subject research. This guidance document was developed as a part of these efforts and in consultation with OHRP.

In the **Federal Register** of November 20, 2012 (77 FR 69631), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance, and considered them in preparing the final guidance. In the final guidance, FDA clarified that IRBs, sponsors, and clinical investigators all have responsibility for ensuring that the research complies with applicable laws and regulations and that risks to subjects are minimized. FDA also made changes to confirm that the recommendations in the guidance may be fulfilled by any IRB, whether independent or affiliated with an institution, and whether serving as a local IRB or as the central IRB, and made editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated November 2012, and replaces Question 56 in FDA's guidance entitled ''Institutional Review Boards Frequently Asked Questions—Information Sheet—Guidance for Institutional Review Boards and Clinical Investigators.'' [1]

[1] See *http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm#GeneralQuestions.*

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). None of the collections of information referenced in this guidance are new or represent material modifications to previously approved collections of information. The collections of information under 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information under 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information under 21 CFR part 56 have been approved under OMB control number 0910–0130.

III. Comments

Interested persons may submit either electronic comments regarding this guidance 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 *http://www.regulations.gov* or *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm.*

Dated: August 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20822 Filed 8–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0972]

Strengthening the Operating Framework and Furthering the Objectives of Coalition for Accelerating Standards and Therapies Initiative (U24)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Center for Drug Evaluation and Research (CDER) Data Standards Program. The goal of the CDER Data Standards Program is to strengthen and support the Coalition for Accelerating Standards and Therapies (CFAST) Initiative in its efforts to establish and maintain clinical data standards that will enable FDA reviewers to more efficiently perform efficacy analysis of potential new drugs in therapeutic areas that are important to public health.

DATES: Important dates are as follows:

1. The application due date is August 26, 2013.

2. The anticipated start date is September 15, 2013.

3. The expiration date is August 27, 2013.

ADDRESSES: Submit the paper application to: Kimberly Pendleton-Chew, Grants Management (HFA–500), 5630 Fishers Lane, Rm. 2031, Rockville, MD 20857, and a copy to Fatima Frye, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 1195, Silver Spring, MD 20993. For more information, see section III of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Fatima Frye, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1195, Silver Spring, MD 20993, 301–796–4863; or Kimberly Pendleton-Chew, Office of Acquisition Support and Grants, Food and Drug Administration, 5630 Fishers Lane, Rm. 2031, Rockville, MD 20857, 301–827–9363, email: *Kimberly.Pendleton@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/*