TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
12–210		IEC 60601–1–3 Edition 2.0 2008–01 Medical electrical equipment—Part 1–3: General requirements for basic safety and essential performance—Collateral standard: Radiation protection in diagnostic x ray equipment.	Recognition restored with transition period.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

III. List of Recognized Standards

FDA maintains the Agency's current list of FDA Recognized Consensus Standards in a searchable database that may be accessed directly at our Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*. We will incorporate the modifications and revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. We will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary. Beginning with Recognition List Number: 033, we will no longer announce minor revisions to the list of recognized consensus standards such as technical contact person, relevant guidance, processes affected, Code of Federal Regulations citations, and product codes.

IV. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

V. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards-related documents. After publication in the **Federal Register**, this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 035'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/MedicalDevices.*

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.*

VI. Submission of Comments and Effective Date

Interested persons may submit either electronic or written comments concerning this document or concerning recommendations for additional standards for recognition to the contact person (see **FOR FURTHER INFORMATION CONTACT**). FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 035. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11171 Filed 5–14–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0547]

Guidance for Industry on Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products, Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers.'' It replaces the draft guidance with the same name that published on August 27, 2013 (78 FR 52931). This guidance clarifies stability testing recommendations discussed in International Conference on Harmonisation (ICH) stability guidances Q1A(R2) through Q1E for abbreviated new drug applications (ANDAs) and provides responses to public comments in a questions-and-answers format.

DATES: Submit either electronic or written 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. 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.

Submit electronic comments on the 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: Radhika Rajagopalan, Center for Drug Evaluation and Research (HFD–640),

Food and Drug Administration, 7500 Standish Pl., MPN2, Rm. 243, Rockville, MD 20855, 240–276–8546.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a 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 entitled ''ANDAs: Stability Testing of Drug Substances and Products'' recommending that the generic industry follow the approach to stability testing outlined 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,'' May 1997; (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/GuidanceComplianceRegulatoryInformation/Guidances/ucm065005.htm.* FDA also recommended that industry follow the ICH outlined definitions, glossaries, references, and attachments.

To more effectively address the public comments on the September 2012 draft guidance on ''ANDAs: Stability Testing of Drug Substances and Products,'' we decided to publish a draft guidance in a questions-and-answers format entitled ''ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers.'' The draft of this guidance published on August 27, 2013 (78 FR 52931). We have carefully considered the comments we received on that draft, have updated the draft guidance as appropriate, and are now announcing the availability of the final guidance for industry entitled ''ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers'' that supersedes the draft.

This guidance discusses general issues, drug master files, drug product manufacturing and packaging, amendments to pending ANDA applications, and stability studies, with the intent of clarifying the stability testing data recommendations for ANDAs. In addition, the guidance addresses comments received on the August 2013 draft.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on stability testing of drug substances and products. 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 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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0531]

Hemostatic Medical Devices for Trauma Use; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Hemostatic Medical Devices for Trauma Use.'' FDA is holding this public workshop to obtain information on the current challenges and opportunities related to hemostatic medical devices for use in emergency situations. The goals of the workshop are to discuss factors that contribute to hemostatic medical device performance and reliability and types of studies used to assess bleeding and validate methods to evaluate the severity of bleeding, and to define regulatory pathways for novel products.

Dates and Times: The public workshop will be held on September 3 and 4, 2014, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Allison Kumar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5402, Silver Spring, MD 20993, 301–796–6369, *Allison.Kumar@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by August 22, 2014, at 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the meeting/public workshop will be provided beginning at 7 a.m.