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To more effectively address the public comments on the September 2012 draft guidance on ''ANDAs: Stability Testing of Drug Substances and Products,'' we decided to publish a draft guidance in a questions-and-answers format entitled ''ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers.''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 We have carefully considered the comments we received on that draft, have updated the draft guidance as appropriate, and are now announcing the availability of the final guidance for industry entitled ''ANDAs: Stability Testing of Drug Substances and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

[FR Doc. 2014–11177 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–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.

If you need special accommodations due to a disability, please contact Susan Monahan, (email: *susan.monahan@fda.hhs.gov* or phone: 301–796–5661) no later than August 20, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Allison Kumar to register (see *Contact Person*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

*Streaming Webcast of the Public Workshop:* This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by Wednesday, August 22, 2014. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after August 26, 2014. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm*. To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview*. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

*Requests for Protocols:* In advance of the public workshop, CDRH would like to invite interested stakeholders to submit protocols that describe procedures to evaluate issues (e.g., design, validation, conduct, and analysis) related to the adequacy of studies pertaining to bench testing, animal testing, bleeding severity, human factors, and clinical data collection for hemostatic products. Of particular interest to the Agency are methods for assessing high-risk products used in non-compressible wound hemorrhage.

The intention of collecting these protocols is for the Agency to review the submissions and determine viable solutions and paradigms for assessing the safety and effectiveness of hemostatic devices based on scientifically supported expert stakeholder opinions. The result of such a review will be incorporated into the public workshop for in-depth discussion and consensus potentially leading to guidance from the Agency. Please note that while FDA safeguards study protocols and all proprietary information it receives, the protocols submitted in response to this request for protocols will be shared and potentially discussed publically. The deadline for submitting protocols for this public workshop is June 27, 2014. See the comments section for information on how to submit protocols. Please note that information submitted to the docket will be publically available.

*Comments:* 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. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is October 3, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. 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*.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list).

**SUPPLEMENTARY INFORMATION:**

## I. Background

There exists a large variety of hemostatic products on the market and in development that are being used for or are intended to be used to control potentially life-threatening bleeding in emergency situations when there may be no immediate medical facility nearby. Such devices may fit into various medical device regulatory categories such as the absorbable hemostatic agents (21 CFR 878.4490), externally applied vascular clamps (21 CFR 870.4450), various other class II devices, unclassified products (proposed for classification into class II), and those that may be proposed for other regulatory pathways, such as de novo petitions or PMA applications. There are currently a number of scientific and clinical challenges faced by industry and FDA that hamper the evaluation of such products. These include: The difficulty in measuring severity of bleeding in a consistent, reproducible and/or standardized manner, the lack of a bleeding severity scale (i.e., operationalizing the definition of bleeding severity); the translatability of animal models to the human clinical environment, the fact that different products present unique issues, and the challenge of evaluating innovative products when human clinical data are difficult to obtain.

FDA is organizing a hemostatic medical devices public workshop focused on the current challenges and opportunities with hemostatic medical devices for use in emergency situations. The participants include a broad range of stakeholders that are responsible for the design, testing, manufacturing, regulation, and use of hemostatic devices. Specifically, the public workshop is intended to foster open constructive dialogue:

- On the challenges related to the design, development, evaluation, and use of hemostatic medical devices.
- To facilitate collaboration amongst stakeholders interested in hemostatic medical device development and use.
- To promote development of regulatory science tools for evaluating hemostatic medical devices.

## II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to, the following:

1. The current landscape of products used for emergency treatment of bleeding and the respective Centers, Divisions, and Branches within FDA involved in their review.

2. Definitions of bleeding severity and methods for validating bleeding severity scales used in the evaluation of hemostatic devices.

3. Pre-clinical studies, including animal studies, that can be used to collect data when clinical data are difficult to obtain. What value do these models provide (for the evaluation of hemostatic medical devices?) and what are their shortcomings?

4. What options exist for obtaining clinical data for products used for emergency treatment of bleeding in both Civilian and Military settings, and which devices should be supported by clinical data?

5. Products used for emergency treatment of bleeding are often used by a variety of end users and in a variety of high-stress situations; improper or unnecessary device use has the potential to cause serious harm. What human factors issues exist with use of these products and how should these issues be studied?

6. Discussion of protocols used to study the topics, such as validation of bleeding severity, bench-top, animal, and human studies, and assessment of hemostatic devices used for non-compressible hemorrhage.

These topics will be presented by experts in the associated area, followed by more indepth discussions of the given topics in smaller breakout sessions.

Dated: May 9, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–11170 Filed 5–14–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2013–E–0431; FDA–2013–E–0432; FDA–2013–E–0433; FDA–2013–E–0436; FDA–2013–E–0437; FDA–2013–E–0438; and FDA–2013–E–0439]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; KYPROLIS

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for KYPROLIS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit electronic comments to *http://www.regulations.gov*. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product KYPROLIS (carfilzomib). KYPROLIS is indicated for the treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent and have demonstrated disease progression on or within 60 days of completion of the last therapy. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for KYPROLIS (U.S. Patent Nos. 7,232,818; 7,417,042; 7,491,704; 8,207,125; 8,207,126; 8,207,127; and 8,207,297) from Onyx Therapeutics, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated July 10, 2013, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of KYPROLIS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for KYPROLIS is 2,565 days. Of this time, 2,267 days occurred during the testing phase of the regulatory review period, while 298 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* July 14, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 14, 2005.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 27, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for KYPROLIS (NDA 202714) was submitted on September 27, 2011.

3. *The date the application was approved:* July 20, 2012. FDA has verified the applicant's claim that NDA 202714 was approved on July 20, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 24 days; 43 days; or 462 days of patent term extension.