4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0618]

Draft Guidances Relating to the Development of Biosimilar Products; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 1-day public hearing to obtain input on recently issued draft guidances relating to the development of biosimilar products (draft guidances). These draft guidances were issued by FDA as part of the implementation of the Biologics Price Competition and Innovation Act of 2009 (the BPCI Act). The BPCI Act establishes an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to, or interchangeable with, a reference product. FDA will consider the information it obtains from the public hearing in the finalization of these guidances. In addition, FDA is soliciting public input regarding topics for future policies regarding biosimilars.

DATES: The public hearing will be held on May 11, 2012, from 8:30 am to 5 pm. Individuals who wish to present at the public hearing must register by April 11, 2012. Section V of this document provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993.

Submit electronic comments 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. Identify comments with the corresponding docket number found in brackets in the heading of this document.

Transcripts of the public hearing will be available for review at the Division of Dockets Management and on the Internet at http://www.regulations.gov approximately 30 days after the public hearing (see section VIII of this document).

A live Web cast of this public hearing may be seen at http://www.fda.gov/Drugs/NewsEvents/ucm265628.htm on the day of the public hearing.. A video record of the public hearing will be available at the same Web address for 1 year.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (Affordable Care Act) (Public Law No. 111-148). The Affordable Care Act contains the BPCI Act that amends the Public Health Service Act (the PHS Act) and other statutes to create an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, a reference product (see sections 7001 through 7003 of the Affordable Care Act).

The implementation of an abbreviated licensure pathway for biological products can present challenges given the scientific and technical complexities that may be associated with the larger and often more complex structure of biological products, as well as the processes by which such products are manufactured. Most biological products are produced in a living system such as a microorganism, or plant or animal cells, whereas small molecule drugs are typically manufactured through chemical synthesis.

Among other things, section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, sets forth the requirements for an application for a proposed biosimilar biological product. Section 351(k) defines biosimilarity to mean "that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." A 351(k) biosimilar application must contain, among other things, information demonstrating that the biological product is biosimilar to a reference product based upon data derived from analytical studies, animal studies and a clinical study or studies, unless FDA determines that an element described here is unnecessary in a 351(k) application.

II. Previous Public Hearing on Biosimilar Pathway

As part of our commitment to public outreach, FDA held a 2-day public hearing on the "Approval Pathway for Biosimilar and Interchangeable Biological Products" on November 2 and 3, 2010 (75 FR 61497, October 5, 2010) (November 2010 public hearing). The purpose of that public hearing was to seek comments on a number of issues relating to the implementation of the BPCI Act. Over 40 speakers presented at the public hearing. In addition to the presentations, FDA has received more than 60 public comments to the docket, which closed on December 31, 2010. Information on this prior public hearing, including the Federal Register notice, meeting transcripts, and public comments can be found at http://www.regulations.gov (Docket No. FDA-2010-N-0477). FDA carefully considered the presentations and public comments as it was developing the recently issued draft guidances (see section III of this document).

III. Draft Guidances

FDA has issued the following three draft guidances as part of its initial implementation of the BPCI Act based on public input at the November 2010 public hearing regarding priorities for issuing guidances:

- Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (scientific considerations draft guidance),
- Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 (Q&A draft guidance), and
- Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product (quality considerations draft guidance).

The three draft guidances were published in the Federal Register on February 15, 2012. The scientific considerations draft guidance discusses important scientific considerations in

demonstrating biosimilarity, including the totality-of-the-evidence approach FDA will apply to the review of 351(k) applications and general scientific principles in conducting comparative analyses and studies intended to support a demonstration of biosimilarity.

The Q&A draft guidance provides answers to common questions from sponsors interested in developing proposed biosimilar products, biologics license application (BLA) holders, and other interested parties regarding FDA's interpretation of the BPCI Act.

The quality considerations draft guidance provides recommendations on general principles and specific factors to consider when conducting analytical studies as part of the biosimilarity assessment.

IV. Purpose and Scope of the Public Hearing

The purpose of this public hearing is twofold. First, we wish to receive comments on these three draft guidances from a broad group of stakeholders, such as health care professionals, health care institutions, manufacturers of biomedical products, interested industry and professional associations, patients and patient associations, third party payers, current and prospective BLA and new drug application (NDA) holders, and the public. FDA is seeking feedback, both general and specific, on the scientific considerations, Q&A, and quality considerations draft guidances. For example, FDA would like to know whether the scope of guidance on a particular topic satisfactorily addresses the particular question, whether there are issues FDA could or should have addressed and did not, and whether FDA's thinking on each topic is sufficiently clear to provide meaningful guidance to stakeholders. In addition, FDA welcomes any comments that will help us enhance the usefulness and clarity of these documents.

Second, FDA is interested in obtaining public input regarding the Agency's priorities for development of future policies regarding biosimilars. One of the questions FDA asked at the

November 2010 public hearing included what types of guidance documents for industry should be a priority for the Agency during the early period of implementation. In reviewing the comments received, we noted that many comments suggested the Agency begin with general, overarching guidances describing the general requirements and principles for biosimilar product development. We agree with this approach and have begun with the three draft guidance documents to be discussed at this public hearing.

The Agency is interested in soliciting public input on the Agency's plans for development of future policies regarding biosimilars and whether or not it aligns with stakeholder needs. The Agency is also interested in additional topics that should be considered. Topics currently under consideration for future guidances include the following:

- 351(k) applications seeking a determination of interchangeability,
- Requests for reference product exclusivity,
- Naming issues,
- Clinical pharmacology evaluation of biosimilar products, and
- Q&As Regarding Implementation of BPCI Act (next set of questions and answers)[1].

The Agency is committed to continued public outreach as we move forward in our implementation of the BPCI Act. This notice is part of fulfilling that ongoing commitment.

V. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance is free and will be on a first-come, first-served basis. Individuals who wish to present at the public hearing must register by sending an email to biosimilarspublicmtg@fda.hhs.gov on or before April 11, 2012, and provide complete contact

[1] The Agency is not bound by this list of possible topics for future guidances.

information, including name, title, affiliation, address, email, and phone number. Those without email access may register by contacting Sandra Benton (see FOR FURTHER INFORMATION CONTACT). You should identify each guidance you wish to comment on in your presentation, so that FDA can consider that in organizing the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted for each oral presentation, and the approximate time that each oral presentation is scheduled to begin. FDA will notify registered presenters of their scheduled times, and make available an agenda at http://www.fda.gov/Drugs/NewsEvents/ucm265628.htm approximately 2 weeks prior to the public hearing. Once FDA notifies registered presenters of their scheduled times, presenters should submit an electronic copy of their presentation to biosimilarspublicmtg@fda.hhs.gov by May 1, 2012.

If you need special accommodations because of a disability, please contact Sandra Benton (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

A live Web cast of this public hearing may be seen at http://www.fda.gov/Drugs/NewsEvents/ucm265628.htm on the day of the public hearing. A video record of the public hearing will be available at the same Web address for 1 year.

VI. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Center for Biologics Evaluation and Research, and the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section VIII of this document). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

VII. Request for Comments

Regardless of attendance at the public hearing, interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. 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.

VIII. 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 ADDRESSES). A transcript will also be available in either hard copy 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.

Dated: February 27, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-5070 Filed 03/01/2012 at 8:45 am; Publication Date: 03/02/2012]