4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1037]

Establishing a List of Qualifying Pathogens That Have the Potential to Pose a Serious Threat to Public Health; 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 public hearing to obtain input on establishing a list of qualifying pathogens (i.e., those that have the potential to pose a serious threat to public health), as required under the Food and Drug Administration Safety and Innovation Act (FDASIA). This public hearing is being held to obtain comments from the public to determine the methodology that should be used in developing the list of qualifying pathogens, and to elicit suggestions for adding specific pathogens to the list.

Date and Time: The public hearing will be held on December 18, 2012, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the hearing may be extended or may end early.

Location: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, the Great Room (rm. 1503), 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: Lee Lemley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-7563, FAX: 301-847-8753, email: CDER-GAINPublicMtg@fda.hhs.gov.

Registration: The public hearing is free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register.

If you need special accommodations due to a disability, please contact Lee Lemley (see Contact Person) at least 7 days in advance.

Requests for Oral Presentations: If you wish to make an oral presentation during the public hearing, you must register by submitting either an electronic or written request by close of business on December 3, 2012. You must provide your name, title, business affiliation (if applicable), address, email address, and phone and type of organization you represent (e.g., industry, consumer organization), and a brief summary of the presentation (including the discussion topic(s) that will be addressed) to Lee Lemley (see Contact Person). You should identify which question(s) set forth in section II of this document you wish to address so that FDA can consider that in organizing the presentations.

FDA will notify registered presenters of their scheduled times, and will make available an agenda at http://www.fda.gov/Drugs/NewsEvents/ucm319619.htm. Once FDA notifies registered presenters of their scheduled times, presenters should submit an electronic copy of their presentation to Lee Lemley (see Contact Person) no later than December 12, 2012. Persons registered to make an oral presentation should check in

before the hearing, and are encouraged to arrive early to ensure the designated order of presentation.

A live Webcast of this public hearing will be viewable at the following Web site: https://collaboration.fda.gov/gain121812/. A video record of the public hearing will be available at the same Web site for 1 year.

Comments: Regardless of attendance at the public hearing, interested persons may submit either written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronic comments to http://www.regulations.gov. Submit electronic or written comments by December 3, 2012. You should annotate and organize your comments so that they identify the specific questions to which they refer. 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.

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open until January 25, 2013.

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.

SUPPLEMENTARY INFORMATION:

I. Background

Title VIII of FDASIA (Public Law 112-144), entitled "Generating Antibiotic Incentives Now (GAIN)," amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add new section 505E (21 U.S.C. 355E), among other things. This new section of the FD&C Act is designed to encourage development of treatments for serious or life-threatening infections caused by bacteria or fungi. For an application for a drug that is designated a "qualified infectious disease product" under section 505E(d) of the FD&C Act, section 505E(a) provides an extension of 5 years of market exclusivity to the exclusivity periods provided by sections 505(c)(3)(E)(ii) through (c)(3)(E)(iv) (21 U.S.C. 355(c)(3)(E)(ii) through (c)(3)(E)(iv)), 505(j)(5)(F)(ii) through (j)(5)(F)(iv) (21 U.S.C. 355(j)(5)(F)(ii) through (j)(5)(F)(iv)), 505A (21 U.S.C. 355a), and 527 (21 U.S.C. 360cc) of the FD&C Act. However, as section 505E(c) of the FD&C Act states, not all applications for a "qualified infectious disease product" are eligible for the additional market exclusivity. In addition, an application for a drug designated as a "qualified infectious disease product" is eligible for priority review and fast track status (sections 524A and 506(a)(1) of the FD&C Act (21 U.S.C. 356(a)(1))), respectively.

The term "qualifying infectious disease product" refers to an antibacterial or antifungal human drug that is intended to treat serious or life-threatening infections (section 505E(g) of the FD&C Act). It includes treatments for diseases caused by antibiotic- or antifungal-resistant pathogens (including new or emerging pathogens), or

"qualifying pathogens" listed by the Secretary of the Department of Health and Human Services (and, by delegation, FDA) under section 505E(f) (section 505E(g) of the FD&C Act).

According to the statute, "the term 'qualifying pathogen' means a pathogen identified and listed by the Secretary . . . that has the potential to pose a serious threat to public health, such as[:] (A) resistant [G]ram positive pathogens, including methicillin-resistant Staphylococcus aureus, vancomycin-resistant Staphylococcus aureus, and vancomycin-resistant [E]nterococcus; (B) multi-drug resistant [G]ram[-]negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species; (C) multi-drug resistant tuberculosis; and (D) Clostridium difficile" (section 505E(f)(1) of the FD&C Act). FDA is required under the law to consider four factors in establishing and maintaining the list of qualifying pathogens:

- The impact on the public health due to drug-resistant organisms in humans;
- the rate of growth of drug-resistant organisms in humans;
- the increase in resistance rates in humans; and
- the morbidity and mortality in humans.

(section 505E(f)(2)(B)(i) of the FD&C Act). Furthermore, in determining which pathogens should be listed, consultation with infectious disease and antibiotic resistance experts, including those in the medical and clinical research communities, along with the Centers for Disease Control and Prevention (CDC), is required (section 505E(f)(2)(B)(ii) of the FD&C Act).

II. Purpose and Scope of the Hearing

We are holding this hearing to fulfill the statutory consultation requirement and to obtain public comment on the following issues related to establishing the list of qualifying pathogens described in section 505E(f) of the FD&C Act:

1. FDASIA requires FDA to "consider" the following factors in establishing and maintaining the list of qualifying pathogens:

- The impact on the public health due to drug-resistant organisms in humans;
- the rate of growth of drug-resistant organisms in humans;
- the increase in resistance rates in humans; and
- the morbidity and mortality in humans.

How should these factors be applied to a pathogen to determine whether it should be included in the list?

2. Aside from the considerations noted in question 1 (i.e., those required by section 505(E)(f)(2)(B)(i) of the FD&C Act), are there any other factors FDA should consider when establishing and maintaining the list of qualifying pathogens? If so, how should these factors be applied to a pathogen to determine whether it should be included in the list?

3. Which specific pathogens do you believe should be listed as qualifying pathogens? Provide justification for your recommendations, including how you applied the considerations described in section 505E(f)(2)(B)(i) of the FD&C Act , and any other factors that you considered, in recommending the pathogen for inclusion on the list of qualifying pathogens.

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs (the Commissioner) 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 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 (see 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.

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).

Dated: November 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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