DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0967]

Patient-Focused Drug Development for Nontuberculous Mycobacterial Lung Infections; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for nontuberculous mycobacterial (NTM) lung infections. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of NTM lung infections on daily life and patient views on treatment approaches. FDA is also interested in discussing issues related to scientific challenges in developing drugs to treat NTM lung infections. In the afternoon, FDA will hold a workshop and provide information for and gain perspective from patients and patient advocacy organizations, health care providers, academic experts, and industry on various aspects of clinical development of drug products intended to treat NTM lung infections. The input from this public meeting will help in developing topics for further discussion.

DATES: The public meeting will be held on October 15, 2015, from 9 a.m. to 5 p.m. Please register for the meeting by October 7, 2015. Registration from those individuals interested in presenting comments as part of the panel discussions should be received by September 28, 2015. See the **SUPPLEMENTARY INFORMATION** section for instructions on how to register for the meeting. Submit electronic or written comments to the public docket by December 15, 2015.

ADDRESSES: The meeting and workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Participants must enter through Building 1 and undergo security screening. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments to *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. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at *http://www.fda.gov/Drugs/NewsEvents/ucm453877.htm.*

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993, 301–796–5003, FAX: 301–847–8443, *graham.thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected NTM lung infections as the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patient perspectives on the severity of a disease and the available therapies for these conditions. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments that are part of the reauthorization of PDUFA under Title I of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). The full set of performance commitments is available at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA committed to obtain the patient perspective on 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On July 2, 2015, FDA published a notice (80 FR 38216) in the **Federal Register** announcing the disease areas for meetings in fiscal years 2016–2017, the final 2 years of the PDUFA V time frame. The Agency used several criteria outlined in that notice to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. More information, including the list of disease areas and a general schedule of meetings, is posted at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.*

II. Purpose and Scope of the Meeting

The purpose of this Patient-Focused Drug Development meeting is to obtain input on the symptoms and other impacts of NTM lung infections that matter most to patients, as well as perspectives on current approaches to treating this condition. NTM infections can affect all organs in the body; however, NTM infections primarily affect the lungs, especially in patients with underlying lung disease. Common causes of NTM lung infections include *Mycobacterium avium-intracellulare* and *Mycobacterium abscessus.* Symptoms of NTM lung infections include chronic cough, shortness of breath, blood in sputum, fever, fatigue, loss of appetite, night sweats, and weight loss. There are no FDA-approved therapies for NTM lung infections. Treatment requires a combination of drugs given for prolonged duration. The antibacterial drugs used can cause severe side effects that make treatment of this condition difficult. FDA is committed to working with all stakeholders to develop safe and effective therapies for affected individuals.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**). When submitting comments, if you are commenting on behalf of a child please indicate that you are doing so and answer the following questions as much as possible from the patient's perspective.

Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

1. Of all the symptoms that you experience because of your condition, which 1–3 symptoms have the most significant impact on your life? (Examples may include cough, increased sputum production, shortness of breath, difficulty breathing, chest pain)

2. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include sleeping through the night, daily hygiene, driving, walking/running, exercising, etc.)

- How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days? (Examples may include limitations on the ability to undertake physically strenuous activities, restrictions on the ability to travel, inability to sleep, lack of appetite, fatigue, etc.)

3. How has your condition and its symptoms changed over time?

- Do your symptoms come and go? If so, do you know of anything that makes your symptoms better? Worse?

4. What worries you most about your condition?

Topic 2: Patients' Perspectives on Current Approaches To Treating NTM Lung Infections

1. What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, nebulizers, and other therapies including non-drug therapies)

- What specific symptoms do your treatments address?
- How has your treatment regimen changed over time, and why?

2. How well does your current treatment regimen treat the most significant symptoms of your disease?

- How well do these treatments stop or slow the progression of your disease?
- How well do these therapies improve your ability to do specific activities that are important to you in your daily life?
- How well have these treatments worked for you as your condition has changed over time?

3. What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, need for multiple medications, need for injections, going to the hospital for treatment, etc.)

4. Assuming there is no complete cure for your condition, what specific things would you look for in an ideal treatment for your condition?

In the afternoon, discussion will be related to scientific topics, with the goal of understanding issues that may affect the development of drugs for the treatment of NTM lung infections and identifying topics for future discussion. Discussion topics for the afternoon will include the following: Epidemiology and natural history of NTM lung infections, current treatment considerations, clinical trial designs, and clinical trial endpoints.

III. Attendance and Registration

If you wish to attend this meeting, visit *http://ntmpfdd.eventbrite.com.* Please register by October 7, 2015. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability.

If you need special accommodations because of a disability, please contact Graham Thompson at least 7 days before the meeting.

IV. Comments

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by September 28, 2015. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

FDA will hold an open public comment period to give the public an opportunity to comment. Registration for open public comment will occur at the registration desk on the day of the meeting and workshop on a first-come, first-served basis.

Regardless of attendance at the public meeting, you can submit electronic or written responses to the questions pertaining to topics 1 and 2 to the Division of Dockets Management (see **ADDRESSES**) by December 15, 2015. 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.*

V. Transcripts

As soon as a transcript is available, FDA will post it at *http://www.fda.gov/Drugs/NewsEvents/ucm453877.htm.*

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1182]

Joint Food and Drug Administration/Health Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of the ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada.'' We are making available an interpretative summary, a technical Quantitative Risk Assessment (QRA) report with appendices, a risk-assessment model, and a document responding to public comments that we received regarding the 2013 ''Draft Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada.'' The purpose of the QRA is to evaluate the effect of factors such as the microbiological status of milk, cheese-manufacturing steps, and conditions during distribution and storage on the overall risk of invasive listeriosis to the consumer of soft-ripened cheese in the United States or Canada. The QRA