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.

[FR Doc. 2015–18919 Filed 7–31–15; 8:45 am]

BILLING CODE 4164–01–P

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

makes it possible to evaluate the effectiveness of some process changes and intervention strategies in reducing the risk of listeriosis.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for electronic access to the QRA and related documents.

FOR FURTHER INFORMATION CONTACT: Sherri Dennis, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1914.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 11, 2013 (78 FR 9701), we made available a document entitled ''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.'' We gave interested parties an opportunity to submit comments by April 29, 2013, for us to consider on the approach used, the assumptions made, the modeling techniques, the data used, and the clarity and the transparency of the QRA documentation. We received nearly 100 comments on the draft QRA and have revised the QRA where appropriate (See Refs. 1 to 5).

Elsewhere in this issue of the **Federal Register,** we are issuing a notice requesting comments and scientific data and information that would assist us in understanding potential intervention measures to reduce the risk of foodborne illness from consumption of cheeses manufactured from unpasteurized milk.

II. Electronic Access

The QRA and related documents are available electronically on the FDA Web site at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm, http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm,* and *http://www.regulations.gov.*

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.)**

1. FDA and Health Canada, ''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: Interpretative Summary,'' 2015. Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm* and *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*
2. FDA and Health Canada, ''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: Technical Report,'' 2015. Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm* and *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*
3. FDA and Health Canada, ''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: Technical Report Appendices,'' 2015. Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm* and *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*
4. FDA and Health Canada, ''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: Risk Assessment Model,'' 2015. Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm* and *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*
5. Joint FDA/Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Replies to Public Comments, 2015. Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm* and *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18960 Filed 7–31–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2016

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2016. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2012 (PDUFA V), authorizes FDA to collect user fees for certain applications for the review of human drug and biological products, on establishments where the products are made, and on such products. This notice establishes the fee rates for FY 2016.

FOR FURTHER INFORMATION CONTACT: Robert J. Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202F, Silver Spring, MD 20993–0002, 301–796–7223.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively) establish three different kinds of user fees. Fees are assessed on the following: (1) Certain types of applications and supplements for the review of human drug and biological products; (2) certain establishments where such products are made; and (3) certain products (section 736(a) of the FD&C Act). When certain conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act).

For FY 2013 through FY 2017, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA V. The base revenue amount for FY 2013, which became the base amount for the remaining 4 FYs of PDUFA V, is $718,669,000, as published in the **Federal Register** of August 1, 2012 (77 FR 45639). The FY 2013 base revenue amount is further adjusted each year after FY 2013 for inflation and workload. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will provide one-third of the total revenue to be collected each year.

This document provides fee rates for FY 2016 for an application requiring