

information via the internet at <http://www.regulations.gov>. Submit written comments on the collection of information to the Dockets Management Branch (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.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB

for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

OMB Control Number 0910-0641—
Extension

Section 502(x) of the FD&C Act (21 U.S.C. 352(x)), which was added by the Dietary Supplement and Nonprescription Drug Consumer

Protection Act (Pub. L. 109–462), requires the label of a nonprescription drug product marketed without an approved application in the United States to include a domestic address or domestic telephone number through which a manufacturer, packer, and distributor may receive a report of a serious adverse event associated with the product. The guidance document contains questions and answers relating to this labeling requirement and provides guidance to industry on the following topics: (1) The meaning of “domestic address” for purposes of the labeling requirements of section 502(x) of the FD&C Act; (2) FDA’s recommendation for the use of an introductory statement before the domestic address or phone number that is required to appear on the product label under section 502(x) of the FD&C Act; and (3) FDA’s intent regarding enforcing the labeling requirements of section 502(x) of the FD&C Act.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors whose name (pursuant to section 502(b)(1) of the FD&C Act) appears on the label of a nonprescription drug product marketed in the United States without an approved application.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Including a domestic address or phone number and a statement of its purpose on OTC drug labeling (21 U.S.C. 502(x))	300	3	900	4	3,600

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 10, 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-0967]

Public Meeting on Patient-Focused Drug Development for Huntington’s and Parkinson’s Diseases

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 Huntington’s disease and Parkinson’s disease. 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 Huntington’s disease and Parkinson’s disease on daily life and patient views on treatment approaches. Although these are both neurological diseases, since they are quite distinct, FDA will structure this public meeting into two distinct sessions. The morning session, scheduled from 9 a.m. to 1 p.m., will be

devoted to hearing patient perspectives on the impact of Huntington's disease on daily life and their views on currently available treatment approaches. The afternoon session, scheduled from 1 p.m. to 5 p.m., will be devoted to obtaining patient perspectives on the impact of Parkinson's disease on daily life and patient views on currently available treatment approaches.

DATES: The public meeting will be held on September 22, 2015, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by September 14, 2015 (see **SUPPLEMENTARY INFORMATION** for instructions). Register here to attend the meeting: <https://pfddhuntingtonparkinson.eventbrite.com>. Submit electronic or written comments to the public docket by November 23, 2015.

ADDRESSES: The meeting 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 <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. 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/ucm451807.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 Huntington's disease (HD) and Parkinson's disease (PD) 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 Safety and Innovation Act (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 April 11, 2013, FDA published a notice (78 FR 21613) in the **Federal Register** announcing the disease areas for meetings in fiscal years (FY) 2013 to 2015, the first 3 years of the 5-year 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 and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. By the end of FY 2015, FDA will initiate a second public process for determining the disease areas for FYs 2016 to 2017. 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. Public Meeting Information

A. 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 HD and PD that matter most to patients, as well as perspectives on current approaches to treating these conditions. HD is a fatal genetic disorder that causes the progressive degeneration of nerve cells in the brain, resulting in uncontrolled movements, loss of intellectual faculties, and emotional disturbance. Each child of an HD parent has a 50-50 chance of inheriting the HD gene, and a person

who inherits the HD gene will eventually develop the disease. Physicians may prescribe a number of medications to help control emotional and movement problems associated with HD. While medicines may help keep these clinical symptoms under control, there is no current treatment to stop or reverse the course of the disease.

PD belongs to a group of conditions called motor system disorders, which are the result of the loss of dopamine-producing brain cells. As nerve cells become impaired or die, individuals begin to experience tremor, muscle rigidity or stiffness, slowing of movement, and impaired balance and coordination. The cause of PD is unknown, but factors such as genetics and environmental triggers may play a role. Although there is no cure for PD, medications can help manage the levels of dopamine and other neurotransmitters in the brain to improve symptoms. Deep brain stimulation is a surgery that may also be used to manage symptoms if medications are not effective.

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**).

B. Huntington's Disease Discussion Questions

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 one to three symptoms have the most significant impact on your life? (Examples may include: ability to control movements, balance/coordination, difficulty concentrating, sleeping, mood/behavior, etc.)

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 bathing/showering, cooking, eating, dressing, shopping, etc.)

- How do your symptoms affect your daily life on the best days? On the worst days?

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. How has your condition affected your social interactions, including relationships with family and friends?

- 5. How has your condition affected your mood (for example: depression, apathy, patience/tolerance for frustration)?

Topic 2: Patients' Perspectives on Current Approaches To Treating HD

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

- (a) What specific symptoms do your treatments address?

- (b) 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?

- (a) How well do these treatments improve your ability to do specific activities that are important to you in your daily life?

- (b) 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, interacts with other medications, need to visit your doctor more frequently, etc.)

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

C. Parkinson's Disease Discussion Questions

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 one to three symptoms have the most significant impact on your life? (Examples may include difficulty moving, pain, constipation, difficulty concentrating or remembering, daytime sleepiness, etc.)

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 daily hygiene, feeding, dressing, etc.)

- How do your symptoms affect your daily life on the best days? On the worst days?

3. How has your ability to cope with 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?

5. How has your condition affected your social interactions, including relationships with family and friends?

Topic 2: Patients' Perspectives on Current Approaches To Treating PD

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

- What specific symptoms do your treatments address (for example: depression, constipation, memory difficulty, sleepiness, ability to move)?

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

- How well do these treatments improve your ability to do specific activities that are important to you in your daily life?

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 to visit your doctor or take medications frequently, cause sleepiness, etc.)

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

III. Meeting Attendance and Participation

If you wish to attend this meeting, visit <https://pfddhuntingtonparkinson.eventbrite.com>. Please register by September 14, 2015. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. When you register, you can indicate whether you plan to attend the morning session on HD, the afternoon session on PD, or both. You will also 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 (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

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 8, 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.

IV. Comments

Regardless if you attend the public meeting, you can submit electronic or written responses to the questions pertaining to HD Topics 1 and 2 and PD Topics 1 and 2 to the public docket (see **ADDRESSES**) by November 23, 2015. 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/ucm451807.htm>.

Dated: July 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.