on approximately 10,250 gas containers (''frequency of disclosure'' in table 3), resulting in approximately 41,000,000 labels (''total disclosures'' in table 3). FDA expects that the labeling information currently used by industry is already consistent with the recommendations in the revised draft guidance. As a result, FDA estimates that it will take each person or entity approximately 0.1 hours (''hours per disclosure'' in table 3) to review the information to ensure that their labeling is consistent with the revised draft guidance.

FDA estimates the information collection resulting from the revised draft guidance as follows:

TABLE 1—ESTIMATED REPORTING BURDEN[1]

Form FDA 3864 and other requested information	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total hours
Certification Requests During the First Year	31	2.03	63	2	126
Certification Requests Annually After the First Year	5	1	5	2	10
Total					136

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

TABLE 2—ESTIMATED RECORDKEEPING BURDEN[1]

	Number of recordkeepers	Number of records per recordkeeper	Total records	Average burden per recordkeeping (in hours)	Total hours
Verification and documentation of certified sources by persons or entities who market a medical gas but are neither the original manufacturer nor the original marketer	4,000	3	12,000	0.25 (15 minutes)	3,000

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

	Number of respondents	Frequency of disclosure	Total disclosures	Hours per disclosure	Total hours
Providing documentation of certification	3,500	5	17,500	0.25 (15 minutes)	4,375
Labeling required under section 576(a)(3)(A)(ii) of the FD&C Act	4,000	10,250	41,000,000	0.1 (6 minutes)	4,100,000
Total					4,104,375

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

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: *November 19, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29989 Filed 11–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–4166]

Public Meeting on Patient-Focused Drug Development for Psoriasis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for Psoriasis. 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 psoriasis, including on daily life and patient views on treatment approaches. FDA is interested in patients' perspectives for the types of psoriasis with primarily skin symptoms (such plaque psoriasis, nail psoriasis, guttate psoriasis, etc.), patient views on treatment approaches, and decision factors taken into account when selecting a treatment.

DATES: The public meeting will be held on March 17, 2016, from 10 a.m. to 6 p.m. Registration to attend the meeting must be received by March 10, 2016 (see **SUPPLEMENTARY INFORMATION** for instructions). Submit electronic or written comments to the public docket by May 17, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0418 for ''An Evaluation of the Prescription Drug User Fee Act Workload Adjuster; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FDA will post the agenda approximately 5 days before the meeting at: *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm470608.htm.*

FOR FURTHER INFORMATION CONTACT: Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 240–402–6525, FAX: 301–847–8443, *Meghana.Chalasani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected psoriasis 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 that condition. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments that are part of the reauthorization of the 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 at least 20 disease areas during the course of PDUFA V. For each disease area, the Agency is conducting 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 in the **Federal Register** (78 FR 08441) announcing the disease areas for meetings in fiscal years (FYs) 2013–2015, 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. FDA initiated a second public process for determining the disease areas for FY 2016–2017, and published a notice in the **Federal Register** on July 2, 2015, announcing the selection of eight disease areas. 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

As part of Patient-Focused Drug Development, FDA will obtain patient and patient stakeholder input on the symptoms of psoriasis that matter most to patients and on current approaches to treating psoriasis. Psoriasis is a chronic, immune-mediated skin condition that is associated with both a physical and psychological burden. It is characterized by areas of red, thickened, scaling skin and may be accompanied by itching or soreness. While there is currently no cure, treatments for psoriasis include topical therapies such as corticosteroids

and vitamin D analogs, systemic drugs, biologic products, and phototherapy. FDA is interested in the perspectives of patients with psoriasis on (1) the impact of their skin disease, including the extent and location (*e.g.,* nail, palm, scalp, genital) of involvement, (2) treatment approaches, and (3) decision factors taken into account when selecting a treatment.

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**).

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 red, thickened, scaling skin, itching, burning, or soreness, 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 hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)

(3) How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?

(4) How have your condition and its symptoms changed over time?

(a) Would you define your condition today as being well managed?

(5) What worries you most about your condition?

Topic 2: Patients' Perspectives on Current Approaches to Treatment

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

(a) How has your treatment regimen changed over time, and why?

(2) How well does your current treatment regimen control your condition?

(a) How well do your treatments address specific skin symptoms? Which symptoms are not addressed as well?

(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 going to the hospital or clinic for treatment, time devoted to 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?

(a) What would you consider to be a meaningful improvement (for example symptom improvements or functional improvements) in your condition that a treatment could provide?

(5) What factors do you take into account when making decisions about selecting a course of treatment?

(a) What information on the potential benefits of these treatments factors most into your decision?

(b) How do you weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include headache, nausea, injection site reactions.)

(c) How do you weigh potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are infections, cancer, liver damage, kidney damage, birth defects, blood disorders, etc.)

B. Meeting Attendance and Participation

If you wish to attend this meeting, visit *https://psoriasispfdd.eventbrite.com.* Please register by March 10, 2016. 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 Meghana Chalasani (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 February 29, 2016. 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.

Docket Comments: Regardless of whether you attend the public meeting, you can submit electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**) by May 17, 2016.

Transcripts: As soon as a transcript is available, FDA will post it at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm470608.htm.*

Dated: November 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29992 Filed 11–24–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than January 25, 2016.