complex issues for trial design conduct
and analysis; (3) development of
translational and regulatory science to
support rare disease drug development;
and (4) safety and dosing
considerations, including safety
exposures and assessment of dose
selection.

Topics for discussion on day 2
include: (1) Collaborative research
networks for pediatric rare diseases; (2)
safety considerations for pediatric rare
diseases; (3) pediatric rare cancers; and
(4) development of gene therapies for
rare pediatric disorders. Discussions
will help develop a report that includes
a strategic plan to encourage and
accelerate the development of new
therapies for pediatric rare diseases.

FDA encourages individuals, patients,
advocates, industry, consumer groups,
health care professionals, researchers
and other interested persons to attend
this public workshop.

Dated: September 17, 2013.
Leslie Kux,
Assistant Commissioner for Policy.
[FR Doc. 2013–22959 Filed 9–20–13; 8:45 am]
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DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2013–N–1041]

Fibromyalgia Public Meeting on
Patient-Focused Drug Development

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 fibromyalgia. Patient-Focused Drug Development is
part of FDA’s performance commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is
intended to allow FDA to obtain patients’ perspectives on the impact of fibromyalgia on daily life as well as the
available therapies for fibromyalgia.

DATES: The public meeting will be held
on December 10, 2013, from 1 p.m. to
5 p.m. Registration to attend the meeting
must be received by November 27, 2013.
See the SUPPLEMENTARY INFORMATION
section for information on how to
register for the meeting. Submit
electronic or written comments by
February 10, 2013.

ADDRESSES: The meeting will be held at
the FDA White Oak Campus, 10903
New Hampshire Ave., Building 31
Conference Center, in Section A of the
Great Room (Rm. 1503), Silver Spring,
MD 20993. Entrance for the public
meeting participants is through Building 1,
where routine security check
procedures will be performed. 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/ForIndustry/
UserFees/PrescriptionDrugUserFee/
ucm363203.htm.

FOR FURTHER INFORMATION CONTACT:
Graham Thompson, Center for Drug
Evaluation and Research, Food and
Drug Administration, 10903 New
Hamphire Ave., Bldg. 51, Rm. 1199,
Silver Spring, MD 20993, 301–796–
5003, FAX: 301–847–4443, email:
Graham.Thompson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug
Development

FDA has selected fibromyalgia as the
focus of a meeting under Patient-
Focused Drug Development, an
initiative that involves obtaining a better
understanding of patients’ perspectives
on the severity of the disease and the
available therapies for the condition.
Patient-Focused Drug Development is
being conducted to fulfill FDA’s
performance commitments made as part
of the authorization of PDUFA V under
Title I of the Food and Drug Safety and
Innovation Act (FDASIA) (Pub. L. 112–
144). The full set of performance
commitments is available on the FDA
Web site at http://www.fda.gov/
downloads/orindustry/userfees/
prescriptiondruguserfee/
ucm270412.pdf.

FDA has committed to obtain the
patient perspective in twenty 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
community, and other interested
stakeholders.

On April 11, 2013, FDA published a
notice (78 FR 08441) in the Federal
Register announcing the disease areas
for meetings in fiscal years (FY) 2013–
2015, the first 3 years of the 5-year
PDUFA V timeframe. To develop the list
of disease areas, the Agency used
criteria that were outlined in the
April 11 notice. The Agency obtained
public comment on these criteria and
disease areas through a notice for
public comment published in the
Federal Register on September 24, 2012
(77 FR 23454, and through a public
meeting held on October 25, 2012. In
selecting the disease areas, FDA
carefully considered the public
comments received and the perspectives
of their review divisions. By the end of FY
2015, FDA will initiate another public
process for determining the disease
areas for FY 2016–2017. More
information, including the list of disease
areas and a general schedule of
meetings, is posted on FDA’s Web site
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
symptoms of fibromyalgia that matter
to patients and on current
approaches to treating fibromyalgia.
Fibromyalgia is a chronic disorder
characterized by widespread
musculoskeletal pain and tenderness in
multiple tender points and may be
accompanied by fatigue, sleep
disturbances, irritable bowel syndrome,
headache, and mood disorders. While
there is currently no definitive cure,
treatments for fibromyalgia include
medications and lifestyle changes with
emphasis on minimizing symptoms and
improving general health and daily
function. FDA is interested in obtaining
a better understanding of fibromyalgia
patients’ perspectives on the severity of
the disease and the available therapies
used to treat fibromyalgia and its
symptoms.

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 patient panel discussion will begin
the dialogue, 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 that 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 1–3 symptoms have the most significant impact on your life? (Examples may include chronic pain, fatigue, difficulty concentrating, sleep disorders, 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, driving, household chores, etc.)
(a) How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?
(b) How have your condition and its symptoms changed over time?
(a) Do your symptoms come and go? If so, do you know of anything that makes your symptoms better? Worse?
(b) What worries you most about your condition?

Topic 2: Patients’ Perspectives on Current Approaches to Treating Fibromyalgia

(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 exercise or acupuncture)
(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, going to the hospital for treatment, restrictions on driving, etc.)
(a) What specific things would you look for in an ideal treatment for your condition?
(b) How well have these treatments worked for you as your condition has changed over time?
(4) What specific things would you look for in an ideal treatment for your condition?

B. Meeting Attendance and/or Participation

If you wish to attend this meeting, visit https://patientfocusedfibromyalgia.eventbrite.com. Please register by November 27, 2013. Those who are unable to attend the meeting in person can register to view a live webcast of the meeting. You will be asked to indicate in your registration whether you plan to attend in person or via the webcast. Your registration should also contain your complete contact information, including name, title, affiliation, address, email address, and phone number.

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 disability, please contact Graham Thompson (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the information.

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 will also be asked to send a brief summary of responses to the topic questions to PatientFocused@fda.hhs.gov. Panelists will be notified of their selection soon after the close of registration on November 27, 2013. FDA 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.

Interested members of the public, including those who attend the meeting in person or through the webcast, are invited to provide electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see ADDRESSES). Comments may be submitted until February 10, 2013.

Dated: September 17, 2013.

Leslie Kux,
Assistant Commissioner for Policy.
[FR Doc. 2013–23019 Filed 9–20–13; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2013–N–0001]

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; 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.

Name of Committee: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on October 30, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/default.htm; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: ACPS-CP@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: There will be two topics presented to the committee for their