Patient-Focused Drug Development for lung cancer. 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 patients’ perspectives on the impact of lung cancer on daily life as well as the available therapies for lung cancer.

**DATES:** The public meeting will be held on June 28, 2013, from 8:30 a.m. to 12:30 p.m. Registration to attend the meeting must be received by June 19, 2013 (see SUPPLEMENTARY INFORMATION for instructions). Submit electronic or written comments by July 29, 2013.

**ADDRESSES:** The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants is through Building 1, where routine security checks will be performed. For parking and security information, please refer to http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/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 complete agenda and additional meeting background material approximately 5 days before the meeting at http://www.fda.gov/Forindustry/UserFees/PrescriptionDrugUserFee/ucm353273.htm.

**FOR FURTHER INFORMATION CONTACT:**
Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1199, Silver Spring, MD 20993, 301–796–0684, FAX: 301–847–8443, email: graham.thompson@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:**

**I. Background on Patient-Focused Drug Development**

FDA has selected lung cancer to be the focus of a public 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 performance commitments made as part of the reauthorization 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/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.

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

On April 11, 2013, FDA published a document (78 FR 21613) in the Federal Register that announced the disease areas for meetings in fiscal years (FY) 2013 to 2015. The first 3 years of the 5-year PDUFA V timeframe. The Agency used several criteria outlined in the April 11, 2013, document to develop the list of disease areas. Public comment on the Agency’s proposed criteria and potential disease areas was gathered through a Federal Register document for public comment that was published on September 24, 2012 (77 FR 58849), 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 public process for determining the disease areas for FY 2016 and 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 gather patient and patient stakeholder input on symptoms of lung cancer that matter most to patients and on current approaches to treating lung cancer. Lung cancer is a disease caused by uncontrolled growth of abnormal cells in the tissues of the lung, usually in the cells lining air passages. Lung cancer cells can spread (metastasize) to almost
any other part of the body, such as to
the brain or to bones. Available
therapies for management of lung cancer
falls into two main categories: therapies
to reduce or control the spread of
disease (including surgery, radiation
therapy, conventional chemotherapy,
and targeted therapies), and supportive
care therapies to improve or manage
symptoms of the underlying condition
(lung cancer) or the side effects of
cancer treatments. FDA is interested in
patients’ perspectives for the two main
types of lung cancer (small-cell and
non-small cell lung cancer) on the
importance of disease symptoms,
benefits of treatment approaches, and
possible cancer treatment side effects.

The draft questions that will be asked
of patients and patient stakeholders at
the meeting are provided in the
paragraphs that follow. For each of these
topics, a brief initial patient panel
discussion will begin the dialogue and
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 the public docket (see
ADDRESSES).

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

1. For context, how long ago was your
diagnosis of lung cancer? Is your cancer
currently in only one area of the lung or
has it spread to other parts of the lung
or outside of the lungs?
2. Of all the symptoms that you
experience because of your lung cancer,
which one to three symptoms have the
most significant impact on your daily
life? (Examples may include pain,
cough, shortness of breath, fatigue, voice
hoarseness.)
3. 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 lung cancer? (Examples may
include sleeping through the night,
climbing stairs, household activities.)

Topic 2: Patients’ Perspectives on
Current Approaches To Treating Lung
Cancer

1. Are you currently undergoing any
cancer treatments to help reduce or
control the spread of your lung cancer?
Please describe.
2.1 What do you consider to be the
most significant downsides of these
treatments? (Examples of downsides
may include side effects, going to the
hospital for treatment, frequent blood
tests, etc.)
2.2 How do these downsides affect
your daily life?
2. What supportive care treatments, if
any, are you taking to help improve or
manage the symptoms you experience
because of your lung cancer? Please
include any prescription medicines,
over-the-counter products, and other
therapies including non-drug therapies
(such as breathing techniques).
2.1 What specific symptoms do your
treatments address?
2.2 How well do these treatments
manage these symptoms?
2.3 Are there symptoms that your
current treatment regimen does not
address at all, or does not treat as well
as you would like?
3. When thinking about your overall
goals for treatment, how do you weigh
the importance of prolonging your life
versus improving the symptoms you
experience because of your lung cancer?
4. What factors do you take into
account when making decisions about
using treatments to help reduce or
control the spread of your lung cancer?
In particular:
4.1 What information on the
potential benefits of these treatments
factors most into your decision?
(Examples of potential benefits from
treatments may include shrinking the
tumor, delaying the growth of the
tumor, prolonging life, etc.)
4.2 How do you weigh the potential
benefits of these treatments versus the
common side effects of the treatments?
(Common side effects could include
nausea, loss of appetite, fatigue, diarrhea,
 rash.)
4.3 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 developing a hole in the
stomach or intestine, liver failure,
kidney failure, lung inflammation,
blood clot, stroke, heart attack, serious
infections, etc.)
B. Attendance and/or Participation in
the Meeting
If you wish to attend this meeting,
visit http://patientfocusedlungcancer.
eventbrite.com. Please register by June
19, 2013. Those who are unable to
attend the meeting in person can
register to view a live Web cast of the
meeting. You will be asked to indicate
in your registration if you plan to attend
in person or via the Web cast. Your
registration will 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 meeting. More information
will be posted on the meeting Web site
at least 5 days before the meeting date.

Patients who are interested in
presenting comments as part of the
initial panel discussions should indicate
in their registration which topic(s) they
wish to address. They will be asked to
send a brief summary of responses to
the topic(s) questions via email to
PatientFocused@fda.hhs.gov. Panelists
will be notified of their selection soon
after the close of registration on June 19,
2013. FDA will try to accommodate all
patients and patient advocate
participants 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 Web cast, are
invited to provide electronic or written
responses to any or all of the questions
pertaining to Topics 1 and 2 to the
Division of Dockets Management (see
ADDRESSES). Comments may be
submitted until July 29, 2013.


Leslie Kux,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND
HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood
Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the
Federal Advisory Committee Act, as
amended (5 U.S.C. App.), notice is
hereby given of the following meetings.

The meetings will be closed to the
public in accordance with the
provisions set forth in sections
552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,
as amended. The grant applications
and the discussions could disclose
confidential trade secrets or commercial
property such as patentable material,
and personal information concerning