

strengthen regulatory capacity throughout the Americas in ways that provide benefit and contribution to the FDA regulatory and public health mission. This partnership aligns with FDA's domestic and global goals of addressing medical product safety and quality challenges.

This cooperative agreement will support collaboration and investigation in the following areas:

#### 1. Developing and Applying Regional/Global Norms and Standards

- Enable the sharing of scientific findings and data through expert meetings and technical consultations;
- assist member states in the implementation and subsequent evaluation of internationally-recognized standards and guidelines, e.g. WHO guidelines and standards and those emerging from standards development venues such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH);
- utilize PAHO's convening power to engage with relevant stakeholders on science-based norms and standards; and
- facilitate the alignment and convergence of standards between PAHO, other regions, and/or global bodies.

#### 2. Researching Regulatory Systems Performance

- Contribute to the knowledge base of the current state of medical product regulation globally, including challenges, risks, and emerging trends, and making the business case for investments in regulatory systems; and
- enable and/or further strengthen the development of data/information systems as sources of inputs for evidence-based regulatory decisions and actions and enhanced knowledge management systems, coalitions, and networks.

#### 3. Providing Technical Support to Regulatory Systems Strengthening Efforts and Expand Awareness of the Role of Regulatory Systems in the Broader Global Health Development Framework

- Enable the strengthening of regulatory systems at the regional and global levels in such critical domains as: Regulatory frameworks; marketing authorization; import/export control and postmarket surveillance; inspections; laboratories; pharmacovigilance; clinical trials and vaccine lot release; staff development and training, including the professionalization of the regulatory

workforce; monitoring and evaluation of product quality; inspection and surveillance of products throughout the supply chain; and risk assessment, analysis, and management; and

- contribute strategies to expand the knowledge and awareness of the essential role of regulatory systems within the broader global health and development frameworks, including ways that can leverage existing initiatives, investments and partnerships or catalyze new ones.

#### C. Eligibility Information

This is a single source cooperative agreement. PAHO is eligible to apply for this award. PAHO is the Regional Office for the Americas of WHO. WHO has responsibility for helping to ensure access to essential medical products of assured safety, quality, and efficacy within its 193 member states. It does so in three primary areas: (1) Setting global norms and standards; (2) articulating evidence-based policy options, including those relating to regulatory systems performance; and (3) providing technical support to national and regional regulatory authorities and governments. In recent years, OIP/FDA has been actively engaged with PAHO on a number of areas related to regulatory systems strengthening. OIP/FDA and PAHO are currently involved in a 4-year cooperative agreement which began in September 2010 that promotes medical product regulatory system strengthening in the Americas.

## II. Award Information/Funds Available

#### A. Award Amount

This award is contingent upon FDA appropriations and meritorious application. FDA/OIP can fund one award in the amount up to \$2 million for FY 2015 based on available appropriations.

#### B. Length of Support

The total project period may not exceed 5 years. Funding in future years will be contingent on the availability of appropriations and successful performance in the award not to exceed \$2 million per year.

## III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located <http://www.fda.gov/InternationalPrograms/CapacityBuilding/default.htm>. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent

changes to the Web sites after this document publishes in the **Federal Register**.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 6, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit electronic applications to: <http://www.grants.gov>.

Dated: July 2, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-N-2014-0865]

#### Patient-Focused Drug Development for Idiopathic Pulmonary Fibrosis; Public Meeting; Request for Comments

**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 idiopathic pulmonary fibrosis. 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 idiopathic pulmonary fibrosis on daily life as well as patient views on treatment approaches for idiopathic pulmonary fibrosis.

**DATES:** The public meeting will be held on September 26, 2014, from 1 p.m. to 5 p.m. Registration to attend the meeting

must be received by September 10, 2014 (see **SUPPLEMENTARY INFORMATION** for instructions). Submit electronic or written comments by November 26, 2014.

**ADDRESSES:** The public 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/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm395774.htm>.

**FOR FURTHER INFORMATION CONTACT:**

Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1144, Silver Spring, MD 20993, 301-796-0684, FAX: 301-847-8443, email: [Pujita.Vaidya@fda.hhs.gov](mailto:Pujita.Vaidya@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA has selected idiopathic pulmonary fibrosis 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 PDUFA under Title I of the Food and Drug Administration Safety and Innovation Act (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 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 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 time frame. The Agency used several criteria outlined in the April 11 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 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. Purpose and Scope of Meeting**

The purpose of this Patient-Focused Drug Development meeting is to obtain input on the symptoms and other impacts of idiopathic pulmonary fibrosis that matter most to patients, as well as perspectives on current approaches to treating idiopathic pulmonary fibrosis. FDA expects that this information will come directly from patients, caregivers, and patient advocates. Idiopathic pulmonary fibrosis is a rare and life-threatening disease in which lung tissue become scarred over time. Many people with idiopathic pulmonary fibrosis survive only 3 to 5 years from the time of diagnosis. Symptoms of idiopathic pulmonary fibrosis can include shortness of breath, dry cough, fatigue, and chest pain. There is no cure for idiopathic pulmonary fibrosis; symptomatic treatment options include corticosteroids, oxygen therapy, pulmonary rehabilitation, and lifestyle changes.

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: Symptoms and Daily Impacts That Matter Most to Patients*

- 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 shortness of breath, cough, fatigue, etc.)
- 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 household chores, walking up the stairs, etc.)
  - How do your symptoms and their negative impacts affect your daily life on the best days?
  - How do your symptoms and their negative impacts affect your daily life on the worst days?
  - How has your condition and its symptoms changed over time?

*Topic 2: Patient Perspectives on Treatment Approaches*

- 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.) How well does your current treatment regimen treat the most significant symptoms of your disease?
  - 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, etc.)
  - Because there is no complete cure for your condition, what specific things would you look for in an ideal treatment for your condition?

**III. Attendance and Participation**

If you wish to attend this meeting, visit <http://patientfocusedIPF.eventbrite.com>. Please register by September 10, 2014. If you are unable to attend the meeting in person, you 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 a disability, please contact Pujita Vaidya (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. They will be asked to send a brief summary of responses to the topic questions to [PatientFocused@fda.hhs.gov](mailto:PatientFocused@fda.hhs.gov). Panelists will be notified of their selection a few days after the close of registration on September 10, 2014. 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.

#### IV. Comments

Submit electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**) by November 26, 2014. 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/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm395774.htm>.

Dated: July 2, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0233]

#### Center for Drug Evaluation and Research; Use of Innovative Packaging, Storage, and/or Disposal Systems To Address the Misuse and Abuse of Opioid Analgesics; Reopening of the Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice, reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening the comment period for the notice entitled "Center for Drug Evaluation and Research; Use of Innovative Packaging, Storage, and/or Disposal Systems to Address the Misuse and Abuse of Opioid Analgesics," which published in the **Federal Register** of April 9, 2014. FDA is reopening the comment period to allow interested persons additional time to submit comments.

**DATES:** Submit either electronic or written comments by August 7, 2014.

**ADDRESSES:** 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.

**FOR FURTHER INFORMATION CONTACT:** Colleen Brennan, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Surveillance and Epidemiology, 10903 New Hampshire Ave., Bldg. 22, Rm. 4410, Silver Spring, MD 20993-0002, 301-796-2316, email: [Colleen.Brennan@fda.hhs.gov](mailto:Colleen.Brennan@fda.hhs.gov), with the subject line identified as "Packaging Abuse Deterrence Strategies."

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of April 9, 2014 (79 FR 19619), FDA announced the establishment of a docket to receive suggestions, recommendations, and comments on innovative packaging, storage and disposal systems, technologies or designs that could be used to prevent or deter misuse and abuse of opioid analgesics by patients and others. In the notice, FDA stated that comments about specific system or technology designs should include a description of the following: (1) Design features and functionality; (2) results of any formative or summative human

factors assessments conducted; (3) applications to date, including information on the effectiveness and acceptability of those applications (with literature references or other documentation); (4) recommendations for how the system/technology design could be applied or adapted (either alone and/or in combination with other systems/technologies) to help prevent or deter misuse and abuse, and any limitations of that application; (5) specific problems that could be addressed (e.g., serious complications such as addiction or overdose due to improper dosage and/or administration, improper disposal, accidental use by someone for whom the medication was not prescribed); and (6) to the extent possible, considerations for implementation into routine dispensing and clinical use (e.g., how the solution would impact the workflow in a retail pharmacy).

To help FDA prioritize among proposed approaches, the Agency is also interested in receiving feedback about methods that could be used to assess a system or technology's potential abuse-deterrent characteristics and real-world impact (e.g., actual ability to prevent or deter misuse and abuse, effect on access for appropriate patients, patient confidentiality, burden on the healthcare system, feasibility of implementation, whether the design could create unintended medication errors). Finally, FDA is interested in receiving feedback on methods for encouraging further research and development in this area, and, if promising technologies are identified, incentivizing the pharmaceutical industry (e.g. via patent extensions) to adopt such technologies.

Interested persons were given until June 9, 2014, to submit comments. On our own initiative, the Agency is reopening the comment period until August 7, 2014 to allow interested persons additional time to submit comments. The Agency believes that an additional 30 days allows adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

##### II. How To Submit Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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