

applied the identified criteria in making recommendations for additional disease areas to consider.

FDA also welcomes public comment on the criteria for disease area selection. These criteria include the following:

- Disease areas that are chronic, symptomatic, or affect functioning and activities of daily living;
- Disease areas that reflect a range of severity;
- Disease areas for which aspects of the disease are not formally captured in clinical trials;
- Disease areas that have a severe impact on identifiable subpopulations (such as children or the elderly);
- Disease areas that represent a broad range in terms of size of the affected population; or
- Disease areas for which there are currently no therapies or very few therapies, or the available therapies do not directly affect how a patient feels, functions, or survives.

FDA will consider the public comments received at the public meeting and through the docket and post the set of disease areas for FY 2013–2015 on the FDA Web site. By the end of FY 2015, FDA will initiate a public process for determining the list of disease areas for FY 2016–2017.

III. Public Meeting

FDA is holding a public meeting that will begin FDA's patient-focused drug development initiative in PDUFA V. The purpose of this meeting will be to obtain public comment on the preliminary list of potential disease areas and the criteria used to develop the list. In addition, recognizing that there are many more disease areas than can be addressed in the 20 planned FDA meetings for PDUFA V, FDA will also discuss strategies that have already been pursued by patient and other public stakeholder collaborations outside of FDA to address the types of questions being considered under the PDUFA patient-focused drug development effort, to review lessons learned and identify a roadmap that could be used by patient-focused private collaborations going forward.

If you wish to attend this meeting, please register by email to PatientFocused@fda.hhs.gov by October 18, 2012. Your email should contain 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 Andrea Tan (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Dated: September 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Division of Intramural Research Board of Scientific Counselors, NIAID.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Allergy and Infectious Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Division of Intramural Research Board of Scientific Counselors, NIAID.

Date: December 10–12, 2012.

Time: December 10, 2012, 7:45 a.m. to 6:25 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 50, 50 Center Drive, Room 1227/1233, Bethesda, MD 20892.

Time: December 11, 2012, 7 a.m. to 6:25 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 50, 50 Center Drive, Room 1227/1233, Bethesda, MD 20892.

Time: December 12, 2012, 7 a.m. to 11 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 50, 50 Center Drive, Room 1227/1233, Bethesda, MD 20892.

Contact Person: Kathryn C. Zoon, Ph.D., Director, Division of Intramural Research, National Institute of Allergy and Infectious Diseases, NIH, Building 31, Room 4A30, Bethesda, MD 20892, 301–496–3006, kzoon@niaid.nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 18, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Director's Consumer Liaison Group.

Date: October 25–26, 2012.

Time: 9 a.m. to 1 p.m.

Agenda: October 25, 2012—Improving Uptake of Research Findings; October 26, 2012—NCI Update.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Kelli Marciel, Director, Office of Advocacy Relations, National Cancer Institute, National Institutes of Health, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, 301–594–3194.

Any interested person may file written comments with the committee by forwarding