and Procedures; Fiscal Years 2013 through 2017,'' the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) agreed to publish a joint guidance for industry and review staff on best practices for communication between IND sponsors and FDA during drug development.

To establish the best practices described in this guidance, CDER and CBER gathered the experiences of review staff and incorporated input from interested parties who responded to a notice published in the **Federal Register** (79 FR 64397; October 29, 2014) or who provided input directly to CDER's Enhanced Communication Team.

This guidance describes FDA's philosophy regarding timely interactive communication with IND sponsors as a core activity; the scope of appropriate interactions between the review team and the sponsor; the types of advice appropriate for sponsors to seek from FDA in pursuing their drug development program; the general expectations for the timing of FDA response to IND sponsor inquiries; best practices and communication methods to facilitate interactions between the FDA review team and the IND sponsor during drug development; and expectations on appropriate methods and frequency of such communications. This guidance does not apply to communications or inquiries from industry trade organizations, consumer or patient advocacy organizations, other government agencies, or other stakeholders not pursuing a development program under an IND.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on best practices for communication between IND sponsors and FDA during drug development. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

## III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,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

Dated: December 3, 2015.

**Peter Lurie,**

*Associate Commissioner for Public Health Strategy and Analysis.*

[FR Doc. 2015–30931 Filed 12–8–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–0001]**

### Psychopharmacologic Drugs Advisory Committee; 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:* Psychopharmacologic Drugs Advisory Committee.

*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 January 12, 2016, 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. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

*Contact Person:* Jennifer Shepherd, 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, *PDAC@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:* The committee will discuss new drug application (NDA) 204442, PROBUPHINE (buprenorphine hydrochloride and ethylene vinyl acetate) subdermal implant, submitted by Braeburn Pharmaceuticals, Inc., on behalf of Titan Pharmaceuticals for the proposed indication of maintenance treatment of opioid dependence.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 28, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 17, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 18, 2015.

Persons attending FDA's advisory committee meetings are advised that the

Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jennifer Shepherd at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: *December 3, 2015.*

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015–30970 Filed 12–8–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Pandemic Influenza Medical Countermeasures—Amendment

**ACTION:** Notice of Amendment to the October 17, 2008, Declaration under the Public Readiness and Emergency Preparedness Act, as amended June 11, 2009; the December 22, 2008, Declaration under the Public Readiness and Emergency Preparedness Act, and the February 29, 2012, Declaration under the Public Readiness and Emergency Preparedness Act.

**SUMMARY:** The Secretary is amending the declarations issued on October 10, 2008 (73 FR 61861), as amended June 11, 2009 (74 FR 29213); December 17, 2008 (73 FR 78362); and February 29, 2012 (77 FR 13329), pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to: Cover vaccines, antivirals, diagnostics and devices used against pandemic influenza A viruses in a single declaration; extend coverage to additional antivirals and devices and to biologics and other drugs; simplify descriptions of covered diagnostics and devices; clarify the disease threat and description of pandemic influenza A viruses and influenza A viruses with pandemic potential; include coverage for countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360bbb–3a and 360bbb–3b); extend the effective time period of the prior declarations; reformat the declarations for antivirals and for diagnostics and devices; modify or clarify terms of the declarations; and republish the prior declarations as a single declaration in its entirety, as amended.

**DATES:** The amendment of the October 10, 2008, declaration as amended June 11, 2009, the December 17, 2008, declaration and February 29, 2012, declaration is effective as of January 1, 2016.

**FOR FURTHER INFORMATION CONTACT:** Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201; Telephone 202–205–2882.

**SUPPLEMENTARY INFORMATION:**

### Background

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, though publication in the **Federal Register**, amend any portion of a declaration. Using this authority, the Secretary issued several declarations for countermeasures against pandemic influenza: (1) An October 10, 2008, declaration covering the neuraminidase class of antivirals Oseltamivir Phosphate (*e.g.,* Tamiflu) and Zanamivir (*e.g.* Relenza) (hereinafter, ''antivirals declaration''); (2) a December 17, 2008, declaration covering pandemic influenza diagnostics, personal respiratory protection devices, and respiratory support devices (hereinafter ''diagnostics and other devices declaration''); and a February 29, 2012, amended declaration covering pandemic influenza vaccines (hereinafter, ''vaccines declaration'') and is amending these declarations.[1]

The major actions taken by this amendment to the pandemic influenza countermeasures declarations include the following: (1) Issuing a single declaration to cover vaccines, antivirals, diagnostics and other devices used against pandemic influenza A viruses; (2) extending coverage to additional antivirals and devices and to biologics and other drugs; (3) updating the description of Covered Countermeasures to include those authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act;[2] (4) clarifying the disease threat and the description of pandemic influenza A viruses and influenza A viruses with pandemic potential; (5) changing the description of qualified persons to include persons authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act; (6) clarifying that liability immunity for antivirals, diagnostics and other devices extends to other transactions and to activities related to any federal agreements including clinical trials agreements by adding the terms ''other transactions'' and ''other federal agreements'' to the clause describing the types of federal agreements for which immunity is in effect; (7) deleting references to specific federal contracts in the antivirals declaration to clarify that immunity is not limited to activities conducted under listed contracts; (8) clarifying that liability immunity extends to activities directly conducted by the federal government by adding the phrase ''or directly conducted by the federal Government'' to the section describing methods of distribution for which liability immunity is in effect; (9) narrowing the definition of ''administration'' in the antivirals declaration and in the diagnostics and other devices declaration to cover ''slip-and-fall'' claims only to the extent they are directly tied to the operation of a countermeasure program; (10) extending the time period for which liability immunity is in effect for all of the Covered Countermeasures to December 31, 2022, and; (11) changing the antivirals declaration and the diagnostics and other devices declaration to the format used for the February 29, 2012, amendment to the declaration for pandemic influenza. Other minor modifications and clarifications are also made, as more fully explained below.

The vaccines, antivirals, and diagnostics and other devices declarations are republished as a single pandemic influenza countermeasures declaration (hereinafter, ''declaration'') in full. We explain the substantive and format changes in this supplementary section.

[1] 73 FR 61861, 73 FR 78362, 74 FR 29213, 77 FR 13329.

[2] 21 U.S.C. 360bbb–3a and 360bbb–3b.