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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2016-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 March 29, 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: 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, 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 the specific risk-benefit profile for new drug application (NDA) 207318, NUPLAZID (pimavanserin) 17 milligram (mg) immediate-release, film-coated oral tablets, submitted by Acadia Pharmaceuticals Inc., for the proposed treatment of psychosis associated with Parkinson's disease.

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 March 15, 2016. 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 March 7, 2016. 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 March 8, 2016.

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 Kalyani Bhatt

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: January 27, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016-01752 Filed 1-29-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of the Secretary**

[Document Identifier: HHS-OS-0990-XXXX-60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before April 1, 2016.

ADDRESSES: Submit your comments to Information.CollectionClearance@hhs.gov or by calling (202) 690-6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.CollectionClearance@hhs.gov or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS-OS-0990-XXXX-60D for reference.

Information Collection Request Title: Surgeon General's Pledge to Stem the Opioid Epidemic

Abstract: The Office of the Surgeon General, Office of the Secretary, Department of Health and Human

Services (HHS) requests that the Office of Management and Budget (OMB) approve an information request for the Surgeon General's Pledge to Stem the Opioid Epidemic. This information request involves collecting information

from users for this pledge which recruits doctors, dentists, nurses, and physician assistants to utilize their unique position in the community and in their practice to take notice of the opioid

crisis and commit to taking action that could save lives.

Likely Respondents: Physicians, dentists, physician assistants, nurses, nurse practitioners.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

| Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|--------------|-----------------------|------------------------------------|--|--------------------|
| Pledge | 10,000 | 1 | 0.067 | 670 |

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor,
Information Collection Clearance Officer.
 [FR Doc. 2016-01750 Filed 1-29-16; 8:45 am]
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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R8-ES-2016-N001;
 FXES11120800000-167-FF08EVEN00]

Receipt of Application for Renewal of Incidental Take Permit for Ohlone Tiger Beetle; Low-Effect Habitat Conservation Plan for the Santa Cruz Gardens Unit 12 Project Site; Soquel, Santa Cruz County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit renewal application; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received an application from HPH Properties, L.P. (applicant), for a renewal of incidental take permit TE189382-1 under the Endangered Species Act of 1973, as amended (Act). The applicant has requested a renewal that will extend permit expiration by 6 years from the date the permit is reissued. The applicant has agreed to follow all of the existing low-effect habitat conservation plan (HCP) conditions. If renewed, no additional take will be authorized. The permit would authorize take of the

federally endangered Ohlone tiger beetle (*Cicindela ohlone*), incidental to otherwise lawful activities associated with the Santa Cruz Gardens Unit 12 residential development.

DATES: Written comments should be received on or before March 2, 2016.

ADDRESSES: Obtaining Documents: You may obtain a copy of the permit renewal application and the HCP by writing to the Ventura Fish and Wildlife Ecological Services Office, Attn: Permit number TE189382-1, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003. In addition, we will make the permit renewal application and HCP available for public inspection by appointment during normal business hours at the above address.

Submitting Comments: Please address written comments to Steve Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003. Comments may also be sent by facsimile to (805) 644-3958.

FOR FURTHER INFORMATION CONTACT: Lena Chang, Fish and Wildlife Biologist, Ventura Fish and Wildlife Office, at the above address or by calling (805) 644-1766.

SUPPLEMENTARY INFORMATION: We have received an application from HPH Properties, L.P., for a renewal of incidental take permit TE189382-1 for the endangered Ohlone tiger beetle under the Act. The applicant has requested a renewal that will extend the permit expiration by 6 years. The applicant has agreed to follow all of the existing HCP conditions. If the permit is renewed, no additional take will be authorized. The permit would authorize take of the federally endangered Ohlone tiger beetle, incidental to otherwise lawful activities associated with the Santa Cruz Gardens Unit 12 residential development. In addition to the Ohlone tiger beetle, the HCP includes two plants: The federally threatened Santa Cruz tarplant (*Holocarpha macradenia*)

and Gairdner's yampah (*Perideridia gairdneri* ssp. *gairdneri*), classified as a Rank 4 rare plant by the California Native Plant Society.

Background

The Ohlone tiger beetle was listed by the U.S. Fish and Wildlife Service as endangered on October 3, 2001. Section 9 of the Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations prohibit the "take" of fish or wildlife species listed as endangered or threatened. "Take" is defined under the Act to include the following activities: "[T]o harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (16 U.S.C. 1532); however, under section 10(a)(1)(B) of the Act, we may issue permits to authorize incidental take of listed species. "Incidental Take" is defined by the Act as take that is incidental to, and not the purpose of, carrying out of an otherwise lawful activity. Regulations governing incidental take permits for threatened and endangered species are, respectively, in the Code of Federal Regulations at 50 CFR 17.32 and 17.22. Issuance of an incidental take permit also must not jeopardize the existence of federally listed fish, wildlife, or plant species. All species included in the incidental take permit would receive assurances under our "No Surprises" regulations (50 CFR 17.22(b)(5) and 17.32(b)(5)).

On July 21, 2014, incidental take permit TE189382-0 was transferred from the original permittee, Porter-Livingston Development, Inc. and O'Hara-Balfour LP, to a new permittee, HPH Properties, L.P. Subsequently, a new permit number, TE189382-1, was issued. HPH Properties, L.P. has applied for renewal of a permit for the incidental take of the endangered Ohlone tiger beetle. The potential taking would occur incidental to development of nine new single-family residences at an undeveloped 58.6-acre project site