Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, Subparts A and E), disclosures of such PHI that are otherwise authorized by these routine uses may only be made if and as permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information'' (see 45 CFR 164.512(a)(1)).

The disclosures authorized by publication of the above routine uses pursuant to 5 U.S.C. 552a(b)(3) are in addition to other disclosures authorized directly in the Privacy Act at 5 U.S.C. 552a(b)(2) and (b)(4)–(11).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

All records are stored in an information technology (IT) system.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

All data collected on Medicaid recipients, Medicare beneficiaries, and any non-Medicaid individuals are retrieved by the individual's name, Medicare beneficiary identifier (MBI), health insurance claim number (HICN), SSN, address, and date of birth. The data collected on Medicaid providers will be retrieved by the provider's name, address, National Provider Identifier (NPI), TIN/EIN and other identifying provider numbers. Information about third party data submitters who are individuals will be retrieved by name, address, and TIN/EIN. Records about contact persons will be retrieved by name, email address and business address.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

CMS will retain identifiable T–MSIS data for a period of 10 years after the final determination of the applicable enrollment, eligibility, or claim is completed. Any claims-related records encompassed by a document preservation order may be retained longer (*i.e.,* until notification is received from the Department of Justice).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

CMS has safeguards in place to prevent records from being accessed by unauthorized persons and monitors authorized users to ensure against excessive or unauthorized use. Examples of these safeguards include: protecting the facilities where records are stored or accessed with security guards, badges and cameras, securing hard-copy records in locked file cabinets, file rooms or offices during off-duty hours, limiting access to electronic databases to authorized users based on roles and two-factor authentication (user ID and password), using a secured operating system protected by encryption, firewalls, and intrusion detection systems, requiring encryption for records stored on removable media, and training personnel in Privacy Act and information security requirements. Records that are eligible for destruction are disposed of using destruction methods prescribed by NIST SP 800–88. Before disclosing records to a party outside CMS, CMS requires the intended recipient to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems, and to prevent unauthorized access.

RECORD ACCESS PROCEDURES:

An individual seeking access to a record about him/her in this system of records must submit a written request to the System Manager indicated above. The request must contain the individual's name and particulars necessary to distinguish between records on subject individuals with the same name, such as NPI or TIN, and should also reasonably specify the record(s) to which access is sought. To verify the requester's identity, the signature must be notarized or the request must include the requester's written certification that he/she is the person he/she claims to be and that he/she understands that the knowing and willful request for or acquisition of records pertaining to an individual from an agency under false pretenses is a criminal offense subject to a $5,000 fine. Additionally, in order to locate the record(s), the individual's name and SSN are required.

CONTESTING RECORD PROCEDURES:

Any subject individual may request that his/her record be corrected or amended if he/she believes that the record is not accurate, timely, complete, or relevant or necessary to accomplish a Department function. A subject individual making a request to amend or correct his record shall address his request to the System Manager indicated, in writing, must verify his/her identity in the same manner required for an access request, and must provide his/her name and SSN for the purpose of locating the record. The subject individual shall specify in each request: (1) The system of records from which the record is retrieved; (2) The particular record and specific portion which he/she is seeking to correct or amend; (3) The corrective action sought (*e.g.,* whether he/she is seeking an addition to or a deletion or substitution of the record); and, (4) His/her reasons for requesting correction or amendment of the record. The request should include any supporting documentation to show how the record is inaccurate, incomplete, untimely, or irrelevant.

NOTIFICATION PROCEDURES:

Individuals wishing to know if this system contains records about them should write to the System Manager indicated above and follow the same instructions under Record Access Procedures.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

71 FR 65527 (Nov. 8, 2006), 78 FR 32257 (May 29, 2013), 83 FR 6591 (Feb. 14, 2018).

[FR Doc. 2019–01157 Filed 2–5–19; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0060]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document. Consistent with FDA's regulation, notice is being published with less than 15 days prior to the date of the meeting based on a determination that an immediate meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee is needed. This **Federal Register** notice could not be published 15 days prior to

the date of the meeting due to the lapse of appropriations that began on December 22, 2018. Notice was provided on the Agency website on February 1, 2019, at *https://www.fda.gov/AdvisoryCommittees/Calendar/ucm630167.htm.*

DATES: The meeting will be held on February 12, 2019, from 8 a.m. to 5 p.m.

ADDRESSES: 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: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2019–N–0060. The docket will close on February 11, 2019. Submit either electronic or written comments on this public meeting by February 11, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 11, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 11, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before February 11, 2019, will be provided to the committees.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–0060 for ''Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: 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, email: *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 FDA's website at *https://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.

SUPPLEMENTARY INFORMATION:

Agenda: The committees will discuss the efficacy, safety, and risk-benefit profile of new drug application (NDA) 211243, esketamine 28 mg single-use nasal spray device, submitted by Janssen Pharmaceuticals, Inc., for the treatment of treatment-resistant depression.

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 website 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 website after the meeting. Background material is available at *https://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 committees. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before February 11, 2019, will be provided to the committees. 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 February 7, 2019. 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 February 8, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

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 (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://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: February 1, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01232 Filed 2–5–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0101]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug User Fee Cover Sheet; Form FDA 3397

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 8, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0297. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug User Fee Cover Sheet; Form FDA 3397

OMB Control Number 0910–0297—Extension

Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), as amended, FDA has the authority to assess and collect user fees for certain drug and biologics license applications (BLAs). Under this authority, pharmaceutical companies pay a fee for certain new human drug applications (NDAs) and BLAs submitted to the Agency for review. Because the submission of prescription drug user fees concurrently with applications is required, review of an application by FDA cannot begin until the fee is submitted. The Prescription Drug User Fee Cover Sheet, Form FDA 3397, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of NDAs and BLAs.

Respondents to this collection of information are drug and biologics manufacturers that submit NDAs and BLAs. Based on FDA's database system for fiscal year (FY) 2017, there are an estimated 155 manufacturers of products subject to the Prescription Drug User Fee Act (Pub. L. 105–115), as amended by the FDA Reauthorization Act of 2017 (Pub. L. 115–52.)

The total number of annual responses is based on the number of application submissions received by FDA in FY 2017. CDER received 250 annual responses that included the following submissions: 218 NDAs and 32 BLAs. CBER received 12 BLAs. The estimated hours per response are based on past FDA experience with the various submissions.

In the **Federal Register** of August 24, 2018 (83 FR 42900), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows: