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.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Psychopharmacologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on February 16, 2017, from 8 a.m. to 5 p.m.

ADDRESSES: College Park Marriott Hotel and Conference Center, 3501 University Blvd. East, Hyattsville, MD 20783. The conference center's telephone number is 301–985–7300. 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.*

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 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.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss new drug application (NDA) 209241, Valbenazine 40 milligram (mg) capsules, for the proposed treatment of Tardive Dyskinesia, submitted by Neurocrine Biosciences, Inc.

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 February 2, 2017. 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 January 25, 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 January 26, 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: December 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31144 Filed 12–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Forms for Use With Applications to the Maternal and Child Health Bureau and Bureau of Health Workforce Research and Training Grants

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than February 27, 2017.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N–39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Forms for Use with Applications to the Maternal and Child Health Bureau and Bureau of Health Workforce Research and Training Grants OMB No. 0906–xxxx—New

Abstract: Currently HRSA is cleared to use the National Institutes of Health's (NIH) Biographical Sketch and Public Health Service (PHS) Inclusion Enrollment forms (0925–0001) for HRSA's SF424 Research & Related (R&R) application package research grants. However, both of these documents contain NIH-specific references. To use the forms, HRSA plans to remove the NIH-specific references and obtain its own OMB control number for the collection of this information.

The current Statement of Appointment (form PHS–2271) is also tailored to NIH programs. HRSA plans to remove references to NIH and where appropriate replace them with references to HRSA for use in the SF424 R&R application package.

Need and Proposed Use of the Information: Currently, there are two Bureaus within HRSA, the Maternal and Child Health Bureau (MCHB) and the Bureau of Health Workforce (BHW), that use the Biographical Sketch. In addition to the Biographical Sketch, MCHB also uses the PHS Inclusion Enrollment form, and BHW uses the Statement of Appointment form as required elements of the SF424 Research & Related application package. These Bureaus plan to modify these forms in slightly different ways to meet the needs of their own research and training grant programs.

In MCHB's research grant programs, the modified Biographical Sketch form will be used by applicants to summarize the qualifications of key personnel on their proposed research team; the grant reviewers will use this information to assess the capabilities of the research team to carry out the research project. MCHB's modified PHS Inclusion Enrollment form will be used by applicants to summarize their expected population of research study participants at the time of submission of their proposal; it will also be used for Enrollment Reporting during the annual Noncompeting Continuation Award. Monitoring Inclusion Enrollment is one important component of ensuring statistically meaningful demographics (race, ethnicity, and gender) among research study participants in MCHB's research grant portfolio. MCHB does not use the Statement of Appointment form, as it does not pertain to the MCHB research program.

Similarly, in BHW the modified Biographical Sketch form will be used by applicants to summarize the qualifications of key personnel proposed as project staff; the grant reviewers will use this information to assess the capabilities of the applicant organization to carry out the proposed project. The modified Statement of Appointment form is used to document the appointment of individuals supported by the award to applicable institutional research and training programs. BHW does not use the PHS Inclusion Enrollment form, as it does not pertain to the BHW training and research programs.

Likely Respondents: Respondents are applicants to HRSA's research programs in MCHB and research and training programs in BHW.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Biographical Sketch for MCHB research grant applicants	200	5	1000	2	2000
PHS Inclusion Enrollment form for MCHB research grant applications	200	1	200	.5	100
Biographical Sketch for BHW training and research grant applicants	1000	5	5000	2	10,000
Statement of Appointment form for BHW training grantees	800	7	5600	.5	2,800
Total	2200	.....	11,800	.....	14,900

HRSA 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.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–31080 Filed 12–23–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Updating the HRSA-Supported Women's Preventive Services Guidelines

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Effective December 20, 2016, the Health Resources and Services Administration (HRSA) updated the HRSA-supported Women's Preventive Services Guidelines for purposes of health insurance coverage for preventive services that address health needs specific to women based on clinical recommendations from the Women's Preventive Services Initiative. This notice serves as an announcement of the decision to update the guidelines as listed below. Please see *https://www.hrsa.gov/womensguidelines2016* for additional information.

FOR FURTHER INFORMATION CONTACT: HRSA, Maternal and Child Health Bureau at email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION: