tablet, 180 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to CALAN SR (verapamil hydrochloride) extended-release oral tablet, 180 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26932 Filed 11–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3631]

Ninth Annual Sentinel Initiative; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Ninth Annual Sentinel Initiative Public Workshop.'' Convened by the Duke-Margolis Center for Health Policy at Duke University and supported by a cooperative agreement with FDA, this 1-day workshop will bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Topics will include an update on the state of FDA's Sentinel Initiative, including an overview of the current state of Sentinel System safety surveillance activities, and uses of the Sentinel System accomplished in 2016. In addition, panelists will discuss the future of the Sentinel System and opportunities to expand its medical product surveillance capabilities. This workshop will also engage stakeholders to discuss current and emerging Sentinel Initiative projects.

DATES: The public workshop will be held on February 2, 2017, from 9 a.m. to 4:30 p.m., Eastern Standard Time (EST). Submit either electronic or written comments by March 2, 2017.

ADDRESSES: *Location:* The public workshop will be held at the Barbara Jordan Conference Center at the Kaiser Family Foundation, 1330 G St. NW., Washington, DC 20005. For additional travel and hotel information, please refer to *https://healthpolicy.duke.edu/events/ninth-annual-sentinel-initiative-public-workshop.* FDA has verified the meeting Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**. There will also be a live Webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Workshop*).

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–3631 for ''Ninth Annual Sentinel Initiative; Public Workshop.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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.'' The Agency 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4343, Silver Spring, MD 20993–0002, 301–796–3714, FAX: 301–796–9832, email: *SentinelInitiative@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Registration: To attend the public workshop, you must register before February 2, 2017, by visiting *https://healthpolicy.duke.edu/events/ninth-annual-sentinel-initiative-public-workshop.* You may also register for the live Webcast by visiting this Web page. There will be no onsite registration. When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. Those without Internet access should contact Carlos Bell to register (See **FOR FURTHER INFORMATION CONTACT**). There is no registration fee for the public workshop. However, registration will be on a first-come, first-served basis because seating is limited. Therefore, early registration is recommended. Upon registering, attendees will receive an confirmatory email, containing event materials. A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of the Barbara Jordan Conference Center at the Kaiser Family Foundation.

If you need special accommodations due to a disability, please contact Joanna Higgison at the Duke-Margolis Center for Health Policy (phone: 908–432–4872, email: *joanna.higgison@duke.edu*) at least 7 days in advance.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast (archived video footage will be available following the workshop at *https://healthpolicy.duke.edu/events/ninth-annual-sentinel-initiative-public-workshop*). Persons interested in viewing the live Webcast must register online by February 1, 2017, at 5 p.m. EST. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, and view the workshop using one connection per location whenever possible. Webcast participants will be sent technical system requirements upon registering. Prior to joining the streaming Webcast of the public workshop, it is recommended that you review these technical system requirements.

Meeting Materials: All event materials will be sent to registered attendees via email before the workshop. The event materials will also be available to view on the Duke-Margolis Web site at *https://healthpolicy.duke.edu/events/ninth-annual-sentinel-initiative-public-workshop.*

Transcripts: Please be advised that transcripts will not be available.

Dated: November 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26934 Filed 11–7–16; 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; The Advanced Education Nursing Traineeship (AENT) Program Specific Data Collection Forms

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects 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 should be received no later than January 9, 2017.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 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: The Advanced Education Nursing Traineeship (AENT) Program Specific Data Collection Forms.

OMB No. 0915–0375, Revision

Abstract: The Advanced Nursing Education Workforce (ANEW) Program is a new program that incorporates elements of the AENT and the Advanced Nursing Education Programs. The current OMB approved Program Specific Data Collection Forms for the former AENT Program will be simplified and used for the ANEW program.

HRSA provides advanced education nursing grants to educational institutions to increase the numbers of advanced education nurses through the ANEW Program. The ANEW Program is authorized by Title VIII, Section 811(a)(2) of the Public Health Service Act, (42 U.S.C. 296j(a)(2)), as amended by Section 5308 of the Patient Protection and Affordable Care Act of 2010, Public Law 111–148. This renewal with revision request includes the Project Abstract, Program Narrative, Attachments, and Tables. The proposed ANEW tables are very similar to the previous AENT tables and include information on program participants such as the projected number of enrollees/trainees receiving traineeship support, projected number of graduates receiving traineeship support for the previous fiscal year, the types of programs they are enrolling into and/or from which enrollees/trainees are graduating, and the distribution of primary care nurse practitioners, primary care clinical nurse specialists, and nurse-midwives who plan to practice in rural and underserved settings. To reduce the reporting burden for applicants, HRSA simplified the tables to focus on the types of providers and practice settings that are included in the statute to determine whether applicants qualify for the preference or special consideration in making awards for this program.

Need and Proposed Use of the Information: The Project Abstract is often distributed to provide information to the public and Congress. HRSA will use this information in determining the eligibility for the statutory funding preference and special consideration and to succinctly capture data for the number of projected students for subsequent years in the project period.

Likely Respondents: Likely respondents are potential applicants for the ANEW program. Eligible applicants for the ANEW program include entities that provide registered nurses with primary care nurse practitioner (NP), primary care clinical nurse specialist (CNS), and nurse-midwife education. Such programs may include accredited schools of nursing, nursing centers, academic health centers, state or local governments, and other public or private nonprofit entities authorized by the Secretary of HHS to confer degrees to RNs for primary care NP, primary care CNS, or nurse-midwife education. Federally recognized Indian Tribal Government and Native American Organizations as well as faith-based or