

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 23, 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 March 15, 2017. 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 16, 2017.

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 Caryn Cohen 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: February 15, 2017.

**Janice M. Soreth,**  
Associate Commissioner for Special Medical Programs.

[FR Doc. 2017-03364 Filed 2-17-17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-0595]

#### Pediatric Postmarketing Pharmacovigilance and Drug Utilization Reviews; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect comments related to the pediatric postmarketing pharmacovigilance and drug utilization reviews of products posted between September 17, 2016, and February 24, 2017, on the FDA Web site, but will not be presented at the March 6-7, 2017, Pediatric Advisory Committee (PAC) meeting. These reviews are intended to be available for review and comment by members of the PAC, interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public.

**DATES:** Submit either electronic or written comments by March 10, 2017. The docket will open on February 27, 2017, and remain open until March 10, 2017.

**ADDRESSES:** You may submit your 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, you 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 submission 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-2017-N-0595 for "Pediatric Postmarketing Pharmacovigilance and Drug Utilization Reviews" that have been posted on the FDA Web site at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm> between September 17, 2016, and February 24, 2017, but will not be presented at the March 6-7, 2017 PAC meeting (82 FR 1345, January 5, 2017). Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://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 <https://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:** Kenneth Quinto, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5145, Silver Spring, MD 20993, 240-402-2221, email: [kenneth.quinto@fda.hhs.gov](mailto:kenneth.quinto@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation.

FDA is establishing a public docket FDA-2017-N-0595 to receive input on pediatric postmarketing pharmacovigilance and drug utilization reviews posted between September 17, 2016, and February 24, 2017, on the FDA Web site at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm>, but will not be presented at the March 6-7, 2017, PAC meeting (82 FR 1345, January 5, 2017). FDA welcomes comments by members of the PAC, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the Pediatric Research Equity Act (Pub. L. 108-155), interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public. The docket will open on February 27, 2017, and remain open until March 10, 2017. These pediatric postmarketing pharmacovigilance and drug utilization reviews are for the following products:

- ALEVE PM (diphenhydramine hydrochloride/naproxen sodium)
- ASTEPRO (azelastine hydrochloride)
- ECOZA (econazole nitrate)
- JETREA (ocriplasmin)
- QUARTETTE (levonorgestrel/ethinyl estradiol and ethinyl estradiol)

- TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
- XERESE (acyclovir/hydrocortisone)

Dated: February 15, 2017.

**Janice M. Soreth,**

*Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request; Nurse Faculty Loan Program, Annual Performance Report Financial Data Form

**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 April 24, 2017.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, 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](mailto: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, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

**Information Collection Request Title:** Nurse Faculty Loan Program, Annual Performance Report Financial Data Form, OMB No. 0915-0314—Revision.

**Abstract:** This collection request is for continued approval of the Nurse Faculty Loan Program's revised Annual

Performance Report (NFLP-APR) Financial Data Form. The form was previously titled as the Nurse Faculty Loan Program, Annual Operating Report (NFLP-AOR).

Section 846A of the Public Health Service Act provides the Secretary of HHS with the authority to enter into an agreement with schools of nursing for the establishment and operation of a student loan fund to increase the number of qualified nurse faculty. Under the agreement, HRSA makes awards to schools for the NFLP loan fund, which must be maintained in a distinct account. A school of nursing makes loans from the NFLP account to students enrolled full-time or, at the discretion of the Secretary, part-time in a master's or doctoral nursing education program that will prepare them to become qualified nursing faculty. Following graduation from the NFLP lending school, loan recipients may receive up to 85 percent NFLP loan cancellation over a consecutive 4-year period in exchange for service as full-time faculty at a school of nursing. The NFLP lending school collects any portion of the loan that is not cancelled and any loans that go into repayment due to default, and deposits these monies into the NFLP loan fund to make additional NFLP loans.

**Need and Proposed Use of the Information:** The online NFLP-APR Financial Data Form is an online form in the HRSA Electronic Handbooks (EHBs) Performance Report module as part of the NFLP, Bureau of Health Workforce performance report (OMB No: 0915-0061, expiration date of 6/30/2019). The revised NFLP-APR financial data form will collect less data from applicants and will no longer include nursing student demographic data. The nursing student demographic data is currently collected under OMB approval number No: 0915-0061. The revised NFLP-APR form will only collect financial data to capture the NFLP loan fund account activity related to financial receivables, disbursements, and borrower account data related to employment status, loan cancellation, loan repayment, and collections. Participating schools will provide HRSA with current and cumulative information on: (1) NFLP loan funds received, (2) number and amount of NFLP loans made, (3) number and amount of loans cancelled, (4) number and amount of loans in repayment, (5) loan default rate percent, (6) number of NFLP graduates employed as nurse faculty, and (7) other related loan fund costs and activities.

The school of nursing must keep records of all NFLP loan fund