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 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ruby Singh, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0794, *ruby.singh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 19, 2022, FDA published a notice announcing the availability of a draft guidance for industry entitled ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern,'' and requesting comments on the proposed GFI.

Interested persons were originally given until March 20, 2023, to comment on the document. The Agency has received a request for an extension of the comment period. The request stated that an additional 90 days would allow interested parties to thoroughly consider the request for input. FDA has considered the request and is extending the comment period for the request for comments for 60 days, until May 19, 2023. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments.

Dated: March 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04562 Filed 3–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4853]

Receipt of Notice That a Patent Infringement Complaint Was Filed Against a Biosimilar or Interchangeable Biosimilar Applicant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing notice that an applicant for a biologics license application (BLA) for a biosimilar or interchangeable biosimilar product submitted under the Public Health Service Act (PHS Act) (a ''subsection (k) applicant'') notified FDA that an action for patent infringement was filed in connection with the applicant's BLA. Under the PHS Act, within 30 days after the subsection (k) applicant is served with a complaint in an action for patent infringement described under the PHS Act, the subsection (k) applicant shall provide the Secretary of HHS with notice and copy of such complaint. FDA is required to publish notice of the complaint in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1132, Silver Spring, MD 20993–0002, 301–796–1042, *Sandra.Benton@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148) on March 23, 2010. The BPCI Act amended the PHS Act and created an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)) sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product.

Section 351(l) of the PHS Act describes certain procedures for exchanging patent information and resolving patent disputes between a subsection (k) applicant and the holder of the BLA reference product. If a subsection (k) applicant is served with a complaint in an action for a patent infringement described in section 351(l)(6) of the PHS Act, the subsection (k) applicant is required to provide the Secretary of HHS with notice and a copy of the complaint within 30 days of service. FDA is required to publish notice of a complaint received under section 351(l)(6)(C) of the PHS Act in the **Federal Register**.

FDA received notice of the following complaint under section 351(l)(6)(C) of the PHS Act: *Regeneron Pharmaceuticals, Inc.* v. *Mylan Pharmaceuticals Inc.,* 1:22–CV–61 (N.D.W. Va., filed August 2, 2022).

FDA has only a ministerial role that is limited to publishing notice of a complaint received under section 351(l)(6)(C) of the PHS Act and does not perform a substantive review of the complaint.

Dated: February 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04583 Filed 3–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0680]

Fosun Pharma USA Inc.; Withdrawal of Approval of Abbreviated New Drug Application for Pemoline Tablets, 18.75 Milligrams, 37.5 Milligrams, and 75 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) 075286 for pemoline tablets, 18.75 milligrams (mg), 37.5 mg, and 75 mg, held by Fosun Pharma USA Inc. (Fosun), 104 Carnegie Center, Princeton, NJ 08540. Fosun requested that approval of this application be withdrawn and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of March 7, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On June 30, 1999, FDA approved ANDA 075286 for pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, for the conditions of use in the labeling of new drug application (NDA) 016832, the reference listed drug on which it relied. On October 24, 2005, the Agency issued a Postmarket Drug Safety Information for Patients and Providers communication entitled ''Information for Healthcare Professionals: Pemoline Tablets and Chewable Tablets (Marketed as CYLERT)'' which concluded the overall liver toxicity risk of CYLERT (pemoline) (NDAs 016832 and 017703) and generic pemoline products outweighed the benefits of these products (*https://wayback.archive-it.org/7993/20171114124349/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126461.htm*).

All holders of approved applications for pemoline products, including Fosun, ceased marketing the products at that time. On April 22, 2019, Fosun requested that FDA withdraw approval of ANDA 075286, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing.

For the reasons discussed above, and in accordance with the applicant's request, approval of ANDA 075286 for pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: March 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04564 Filed 3–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Rural Health Network Development Planning Program

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than April 6, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Rural Health Network Development Planning Performance Improvement and Measurement System Database OMB No. 0915–0384—Revision.

Abstract: The purpose of the Rural Health Network Development Planning Program (Network Planning Program) is to promote the planning and development of integrated health care networks to address the following legislative aims: (i) achieve efficiencies; (ii) expand access to, coordinate, and improve the quality of basic health care services and associated health outcomes; and (iii) strengthen the rural health care system. This program supports 1 year of planning and brings together key parts of a rural health care delivery system, particularly those entities that may not have collaborated in the past, to establish and/or improve local capacity in order to strengthen rural community health interventions and enhance care coordination. HRSA collects information from the Network Planning Program award recipients using approved performance measures. HRSA seeks to revise its approved information collection by increasing the total estimated annual burden hours, due to an increase in the number of program award recipients.

A 60-day notice was published in the **Federal Register** on December 9, 2022, vol. 87, No. 236; pp. 75638–39. There were no public comments.

Need and Proposed Use of the Information: Performance measures for the Network Planning Program serve the purpose of quantifying awardee-level data that conveys the successes and challenges associated with the grant award. These measures and aggregate data substantiate and inform the focus and objectives of the grant program. The approved measures encompass the following principal topic areas: network infrastructure, network collaboration, sustainability, and network assessment. The burden is increasing by 2 hours from the previously approved collection due to an increase in the number of award recipients from 21 to 23.

Likely Respondents: The respondents for these measures are Rural Health Network Development Planning Program award recipients.

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 to 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 ICR are summarized in the table below.

Total Estimated Annualized Burden Hours: