DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2156]

Ferring Pharmaceuticals, Inc.; Withdrawal of Approval of Two Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of two abbreviated new drug applications (ANDAs) from Ferring Pharmaceuticals, Inc. (Ferring). Ferring notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of July 16, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Ferring has informed FDA that the drug products listed in the table are no longer marketed and has requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). Ferring has also, by its request, waived its opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 073598	Menotropins (follicle-stimulating hormone (FSH)/luteinizing hormone (LH)) for Injection, 75 international units (IU)/75 IU per vial.	Ferring Pharmaceuticals, Inc., 100 Interpace Pkwy., Parsippany, NJ 07054.
ANDA 073599	Menotropins (FSH/LH) for Injection, 150 IU/150 IU per vial	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 16, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on July 16, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: June 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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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; Zika Virus Pilot Project, OMB No. 0906–xxxx—NEW

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 has 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.

DATES: Comments on this ICR should be received no later than July 16, 2018.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (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: Zika Virus Pilot Project, OMB No. 0906–xxxx—NEW

Abstract: HRSA is requesting the Organ Procurement and Transplantation Network (OPTN) perform a federally sponsored data collection as part of a pilot project to monitor the testing of deceased potential donors possibly exposed to the Zika virus (ZIKV). The Zika Pilot Project will have a 12-month performance period enabling OPTN to develop a plan to collect data on ways for organ procurement organizations (OPOs) to deploy ZIKV donor screening tests of blood products. The testing is available under an investigational new drug application for use on a voluntary basis in the evaluation of deceased persons as potential solid organ donors. OPTN will conduct an analysis of the data collected under this project to determine the potential effect of making available screening tests for ZIKV, when appropriate, to improve transplant safety. OPTN will convene a group of stakeholders to provide guidance and monitor progress on the ZIKV pilot project.

Need and Proposed Use of the Information: ZIKV is prevalent in several areas of the United States. Currently, there is not a ZIKV screening procedure for OPOs to implement during the organ allocation process. HRSA requested OPTN to conduct a pilot project to monitor the testing of deceased donors potentially exposed to ZIKV. The goals of the pilot project are to:

- Collaborate with experts to define necessary data elements to understand the impact of ZIKV testing in deceased organ donors;
- Deploy a data collection tool to a limited number of OPOs that agree to participate in the pilot project; and
- Assess the ability of OPTN to respond to a public health situation by collecting data from impacted members of the transplant community to assess the national experience.

Likely Respondents: Organ Procurement Organizations.

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