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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of July 16, 2018.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Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 16, 2018.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.

[FR Doc. 2018–12762 Filed 6–13–18; 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; 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

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

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Zika Data Collection Tool	20	58	1,160*	.508	589
Total	20		1,160*		589

*Total number of responses determined by applying the percentage of OPOs participating to the total number of deceased donors during 2016. In addition, donors screened for Zika will be based on OPO specific screening criteria. Since all donors will not be screened, this number represents 35% of the donors recovered at the 20 OPOs. Based on OPTN Data as of November 9, 2017.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–12782 Filed 6–13–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Council of Research Advocates.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

Name of Committee: National Cancer Institute Council of Research Advocates.

Date: June 21, 2018.

Time: 9:30 a.m. to 4:00 p.m.

Agenda: Welcome and Chairman's Remarks, NCI Updates, Legislative Update, Budget Update, and Director's Update.

Place: National Institutes of Health, 31 Center Drive, Building 31, 11A01, Bethesda, MD 20892.

Contact Person: Amy Williams, NCI Office of Advocacy Relations, National Cancer Institute, NIH, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, 240–781–3360, *williaam@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to scheduling difficulties.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: NCRA: *http://deainfo.nci.nih.gov/advisory/ncra/ncra.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 8, 2018.

Michelle D. Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–12730 Filed 6–13–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Hepatology.

Date: July 10, 2018.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jonathan K Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2190, MSC 7850, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Tumor Signaling and Biology.

Date: July 11, 2018.

Time: 11:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ola Mae Zack Howard, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7806, Bethesda, MD 20892, 301–451–4467, *howardz@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Infectious Diseases and Microbiology.

Date: July 12–13, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Westminster, 10600 Westminster Blvd., Westminster, CO 80020.

Contact Person: Tamara Lyn McNealy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of