DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FR Doc. 2018–12762 Filed 6–13–18; 8:45 am]

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

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of July 16, 2018.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

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug Description</th>
<th>Applicant</th>
</tr>
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<tbody>
<tr>
<td>ANDA 073598</td>
<td>Menotropins (follicle-stimulating hormone (FSH)/lutetinizing hormone (LH)) for Injection, 75 international units (IU)/75 IU per vial.</td>
<td>Ferring Pharmaceuticals, Inc., 100 Interpace Pkwy., Parsippany, NJ 07054. Do.</td>
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</table>

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 16, 2018.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