DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–P–2675]

Determination That GYNOREST (Dydrogesterone) Oral Tablets, 5 Milligrams and 10 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that GYNOREST (dydrogesterone) oral tablets, 5 milligrams (mg) and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for GYNOREST (dydrogesterone) oral tablets, 5 mg and 10 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Stefanie Kraus, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6214, Silver Spring, MD 20993–0002, 301–796–9585.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

GYNOREST (dydrogesterone) oral tablets, 5 mg and 10 mg, are the subject of NDA 017388, held by Solvay Pharmaceuticals (Solvay), and initially approved on October 31, 1978. GYNOREST is indicated for amenorrhea and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer.

Solvay never marketed GYNOREST (dydrogesterone) oral tablets, 5 mg and 10 mg, under NDA 017388.[1] In previous instances (see *e.g.,* 72 FR 9763, March 5, 2007, and 61 FR 25497, May 21, 1996), the Agency has determined that, for purposes of §§ 314.61 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale. In a letter dated June 1, 1992, Solvay requested withdrawal of NDA 017388 for GYNOREST (dydrogesterone) oral tablets, 5 mg and 10 mg. In the **Federal Register** of June 25, 1993 (58 FR 34466), FDA announced that it was withdrawing approval of NDA 017388, effective July 26, 1993.

Foley and Lardner LLP submitted a citizen petition dated September 7, 2016 (Docket No. FDA–2016–P–2675), under 21 CFR 10.30, requesting that the Agency determine whether GYNOREST (dydrogesterone) oral tablets, 5 mg and 10 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that GYNOREST (dydrogesterone) oral tablets, 5 mg and 10 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner states that GYNOREST (dydrogesterone) oral tablets, 5 mg and 10 mg, were not withdrawn for reasons of safety and effectiveness because the active pharmaceutical ingredient dydrogesterone and the drug product dydrogesterone tablets have a monograph in the current United States Pharmacopeia, public information indicates that Solvay discontinued the product for commercial reasons, there has been no notice in the **Federal Register** reflecting an Agency determination that the product was withdrawn for reasons of safety or effectiveness, and dydrogesterone oral tablets are being sold in many other countries.

We have carefully reviewed our files for records concerning the withdrawal of GYNOREST (dydrogesterone) oral tablets, 5 mg and 10 mg, from sale. We have also independently evaluated relevant literature and data for possible post-marketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list GYNOREST (dydrogesterone) oral tablets, 5 mg and 10 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to GYNOREST (dydrogesterone) oral tablets, 5 mg and 10 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 28, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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[1] GYNOREST was marketed in the United States under a supplement to NDA 012985 for DUPHASTON (dydrogesterone, oral tablets). Distribution of GYNOREST under the DUPHASTON NDA discontinued around 1981.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4852]

Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.