

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 generally known as the “Orange Book”. Under FDA regulations, a drug is 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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is

voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug product listed in the table in this document is no longer being marketed.

Application No.	Drug	Applicant
NDA 21-180 .....	ORTHO EVRA (norelgestromin/ethinyl estradiol) Transdermal System; 0.15 mg/24hr norelgestromin and 0.035 mg/24hr ethinyl estradiol.	Janssen Pharmaceutical Inc., 920 U.S. Highway 202, Raritan, NJ 08869-0602.

FDA has reviewed its records and, under § 314.161, has determined that the drug product listed in this document was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug product listed in this document in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDA listed in this document are unaffected by the discontinued marketing of the product subject to this NDA. Additional ANDAs that refer to this product may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for norelgestromin/ethinyl estradiol transdermal system should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 23, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-3389]

#### **Determination That PONDIMIN (Fenfluramine Hydrochloride) Tablets, 20 Milligrams and 60 Milligrams, and PONDEREX (Fenfluramine Hydrochloride) Capsules, 20 Milligrams Were 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 PONDIMIN (fenfluramine hydrochloride (HCl)) tablets, 20 milligrams (mg) and 60 mg, and PONDEREX (fenfluramine HCl) capsules, 20 mg, were withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for fenfluramine HCl tablets, 20 mg or 60 mg, or fenfluramine HCl capsules, 20 mg.

#### **FOR FURTHER INFORMATION CONTACT:**

Robin Fastenau, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 240-402-4510.

**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 (FD&C 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.

PONDIMIN (fenfluramine HCl) tablets, 20 mg, and PONDEREX (fenfluramine HCl) capsules, 20 mg, were the subject of NDA 16-618, held by Wyeth Pharmaceuticals, and were initially approved on June 14, 1973. PONDIMIN (fenfluramine HCl) sustained release tablets, 60 mg, was the subject of NDA 16-618, held by Wyeth Pharmaceuticals, and was initially approved in 1982. PONDIMIN and PONDEREX were indicated for treatment of obesity.

In 1997, FDA asked that PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules be withdrawn from the market after receiving new evidence that the products were associated with valvular heart disease (September 15, 1997, FDA Announces Withdrawal Fenfluramine and Dexfenfluramine (Fen-Phen), available on the Internet at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm179871.htm>; see FDA November 1997 Fen-Phen Safety Update Information, available on the Internet at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm072820.htm>). Wyeth Pharmaceuticals subsequently discontinued marketing these products. On October 8, 1998, FDA issued a Notice of Proposed Rulemaking proposing to include certain drug products on a list of drug products that had been withdrawn or removed from the market because such drugs products or components of such drug products had been found to be unsafe or not effective, and which could not be compounded under section 503A of the FD&C Act (63 FR 54082). FDA identified in that notice "all drug products containing fenfluramine hydrochloride." The notice also noted that fenfluramine HCl tablets, formerly marketed as PONDIMIN tablets, were associated with valvular heart disease, and the manufacturer voluntarily withdrew the drug from the market. This proposed rule was finalized in 64 FR 10944 (March 8, 1999), 21 CFR 216.24.

In the **Federal Register** of May 5, 2004 (69 FR 25124), FDA issued a notice that it was withdrawing approval of 92 new drug applications and 49 abbreviated new drug applications, including PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules, under section 505(e) of the FD&C Act. Consistent with § 314.161 and its prior rulemaking on compounded drug products under 21 CFR 216.24, FDA has determined that PONDIMIN (fenfluramine HCl) tablets

and PONDEREX (fenfluramine HCl) capsules were withdrawn from sale for reasons of safety or effectiveness. This determination is consistent with FDA's prior request and Wyeth Pharmaceutical's withdrawal of PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules from the market for reasons of safety or effectiveness. The Agency previously removed PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules from the list of drug products published in the Orange Book. FDA will not accept or approve any ANDAs that refer to these drug products.

Dated: September 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-D-1167]

#### Controlled Correspondence Related to Generic Drug Development; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Controlled Correspondence Related to Generic Drug Development". The guidance document provides information regarding the process by which human generic drug manufacturers and related industry can submit correspondence to FDA requesting information on generic drug development. This guidance also describes FDA's process for providing communications related to such correspondence.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY**

**INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Maryll Toufanian, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 75, Rm. 1684, Silver Spring, MD 20993-0002, 240-402-7944, [Maryll.Toufanian@fda.hhs.gov](mailto:Maryll.Toufanian@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Controlled Correspondence Related to Generic Drug Development". The guidance document provides information regarding the process by which human generic drug manufacturers and related industry can submit correspondence to FDA requesting information on generic drug development. This guidance also describes FDA's process for providing communications related to such correspondence.

Under the provisions of the Generic Drug User Fee Amendments of 2012 (GDUFA), FDA agreed to certain obligations as laid out in the Generic Drug User Fee Act Program Performance Goals and Procedures for fiscal years 2013 through 2017 (the GDUFA Commitment Letter) that accompanies the legislation (Ref. 1). Among those obligations is FDA's commitment to performance metrics for its responses to controlled correspondence for fiscal years 2015 through 2017.

This guidance finalizes the draft guidance announced in the **Federal Register** on August 27, 2014 (79 FR 51180). The Agency considered comments on the draft guidance while finalizing this guidance. Generally, we revised the draft guidance to provide clarifying and explanatory information that will assist human generic drug manufacturers and related industry as they submit controlled correspondence to FDA. Changes from the draft guidance include a description of a process to submit information to update the Agency's Inactive Ingredient Database and a description of enhanced communication to requestors regarding the status of their controlled correspondence.

Two comment threads on the draft guidance benefit from additional