TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2015, THROUGH MARCH 31, 2015—Continued

PMA No., Docket No.	Applicant	Trade name	Approval date
P140017, FDA–2015–M–0266	Medtronic, Inc.	Melody™ Transcatheter Pulmonary Valve (TPV) and Ensemble™ Transcatheter Valve Delivery System.	1/27/2015
P130023, FDA–2015–M–0431	Cohera Medical, Inc.	TissuGlu® Surgical Adhesive	2/3/2015
P010047/S036, FDA–2015–M–0502	NeoMend, Inc.	ProGel™ Pleural Air Leak Sealant	2/13/2015
P140018, FDA–2015–M–0690	Covidien, LLC	VenaSeal™ Closure System	2/20/2015
H130001, FDA–2015–M–0909	Biologics Consulting Group, Inc.	Lixelle Beta 2-microglobulin Apheresis Column.	3/5/2015
P110024, FDA–2015–M–0738	Advanced Circulatory Systems, Inc.	ResQCPR™ System	3/6/2015
P130013, FDA–2015–M–0910	Boston Scientific Corp.	WATCHMAN™ Left Atrial Appendage (LAA) Closure Technology.	3/13/2015

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: September 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24625 Filed 9–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0229]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that Xuriden (uridine triacetate), manufactured by Wellstat Therapeutics Corp., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Larry Bauer, Rare Diseases Program, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4842, FAX: 301–796–9858, *larry.bauer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that Xuriden (uridine triacetate), manufactured by Wellstat Therapeutics Corp., meets the criteria for a priority review voucher. Uridine triacetate is a pyrimidine analog for uridine replacement. Xuriden is indicated for the treatment of hereditary orotic aciduria. Hereditary orotic aciduria is caused by a deficiency in the activity of the pyrimidine pathway enzyme uridine 5′-monophosphate synthase. The disorder is generally characterized by anemia and/or other hematological manifestations, excessive urinary excretion of orotic acid, failure to thrive, and developmental delay.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.*

For further information about Xuriden (uridine triacetate), go to the Drugs@FDA Web site at *http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.*

Dated: *September 24, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24640 Filed 9–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3393]

Determination That ORTHO EVRA (Norelgestromin/Ethinyl Estradiol) Transdermal System, 0.15 Milligrams/24 Hours Norelgestromin and 0.035 Milligrams/24 Hours Ethinyl Estradiol, Was 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 ORTHO EVRA (norelgestromin/ethinyl estradiol) Transdermal System, 0.15 milligrams (mg)/24 hours (hr) norelgestromin and 0.035 mg/24hr ethinyl estradiol was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Ayako Sato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–4191, *Ayako.Sato@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved 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 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.

[FR Doc. 2015–24622 Filed 9–28–15; 8:45 am]

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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.