not to submit an evaluation because the field testing of a plant containing a new protein is conducted in such a way (*e.g.,* on such a small scale, or in such isolated conditions, etc.) that cross-pollination with traditional crops or commingling of plant material is not likely to be an issue. Also, other developers may have previously communicated with us about the food safety of a new plant protein, for example, when the same protein was expressed in a different crop.

For purposes of this extension request, we are re-evaluating our estimate of the annual number of responses that we expect to receive in the next 3 years. We received 12 NPCs during the 5-year period from 2005 through 2009, for an average of 2.4 NPCs per year. However, during the last extension period, we saw a decrease in the number of NPCs submitted by developers, with no NPCs submitted in 2010 through 2014. More recently, we received four NPCs in the first 4 months of 2015. Based on an approximate average from the years 2005 through 2009, and our experience in 2015, we are revising our estimate of the annual number of NPCs submitted by developers to be six or fewer.

The early food safety evaluation for new proteins includes six main data components. Four of these data components are easily and quickly obtainable, having to do with the identity and source of the protein. We estimate that completing these data components will take about 4 hours per NPC. We estimate the reporting burden for the first four data components to be 24 hours (4 hours × 6 responses).

Two data components ask for original data to be generated. One data component consists of a bioinformatics analysis which can be performed using publicly available databases. The other data component involves ''wet'' lab work to assess the new protein's stability and the resistance of the protein to enzymatic degradation using appropriate in vitro assays (protein digestibility study). The paperwork burden of these two data components consists of the time it takes the company to assemble the information on these two data components and include it in a NPC. We estimate that completing these data components will take about 16 hours per NPC. We estimate the reporting burden for the two other data components to be 96 hours (16 hours × 6 responses). Thus, we estimate the total annual hour burden for this collection of information to be 120 hours.

Dated: September 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24620 Filed 9–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–M–2375, FDA–2015–M–0909, FDA–2015–M–0199, FDA–2015–M–0200, FDA–2015–M–0201, FDA–2015–M–0228, FDA–2015–M–0266, FDA–2015–M–0267, FDA–2015–M–0431, FDA–2015–M–0502, FDA–2015–M–0690, FDA–2015–M–0738, FDA–2015–M–0910]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Melissa Torres, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–5576.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2015, through March 31, 2015. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

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

PMA No., Docket No.	Applicant	Trade name	Approval date
P980040/S049, FDA–2014–M–2375	Abbott Medical Optics, Inc.	TECNIS® multifocal 1-piece intraocular lens.	12/17/2014
P140010, FDA–2015–M–0199	Medtronic, Inc.	IN.PACT™ Admiral™ Paclitaxel-coated Percutaneous Transluminal Angioplasty Balloon Catheter.	12/30/2014
P130019, FDA–2015–M–0201	EnteroMedics, Inc.	Maestro® Rechargeable System	1/14/2015
P130025, FDA–2015–M–0200	Koning Corp.	Koning Breast CT (Model CBCT 1000)	1/14/2015
P060001/S020, FDA–2015–M–0228	ev3, Inc.	Protégé™ GPS Self-Expanding Peripheral Stent System.	1/21/2015
H140001, FDA–2015–M–0267	ABIOMED, Inc.	Impella RP System	1/23/2015

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