method for sponsors to provide only the information required by § 316.20 for FDA to make a decision.

During this public health emergency associated with the COVID–19 pandemic, the OOPD is providing sponsors with increased flexibility for submission of orphan drug designation requests and related submissions (amendments, annual reports, etc.). During this public health emergency, orphan drug designation, humanitarian use device designation, and rare pediatric disease designation requests and submissions may be submitted electronically by email to the OOPD. When transmitting information to the Orphan Drug Designation Program via email, please utilize the mailbox *orphan@fda.hhs.gov*. We recommend using the automated read receipt feature to avoid having to call to verify receipt of the email. We also strongly encourage sponsors and others who plan to email information to FDA that is considered to be private, sensitive, proprietary, or commercial confidential to send it from an FDA-secured email address, which is provided by FDA, so the transmission is encrypted. The OOPD will assume that the addresses of emails received or email addresses provided as a point of contact are FDA secure when responding to those email addresses.

In the **Federal Register** of October 2, 2020 (85 FR 62306), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Content and format of a request for designation; request for verification of status; amendment to designation	534	1.25	668	135	90,180
§§ 316.20, 316.21, 316.26 (Form FDA 4035)	534	1.25	668	32	21,376
§ 316.22; Notifications of changes in agents	132	1	132	2	264
§ 316.24(a); Deficiency letters and granting orphan-drug designation	20	1	20	2	40
§ 316.27; Submissions to change ownership of orphan-drug designation	104	1	104	5	520
§ 316.30; Annual reports	744	1	744	3	2,232
§ 316.36; Assurance of the availability of sufficient quantities of the orphan drug; holder's consent for the approval of other marketing applications for the same drug	1	3	3	15	45
Guidance Recommendations: Meeting requests to OOPD and related submission packages	2,508	1	2,508	3.595	9,016
Total					123,673

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on our evaluation, we have adjusted the currently approved burden estimate we attribute to information collection activities associated with our Orphan Drug program to reflect an increase in submissions. This notice corrects the mathematical error published in the 60-day notice, which indicated that the total burden was 123,623.

Dated: December 17, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28349 Filed 12–22–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2267]

Endo Pharmaceuticals, Inc.; Withdrawal of Approval of a New Drug Application for OPANA (Oxymorphone Hydrochloride) Extended-Release Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the new drug application (NDA) for OPANA (oxymorphone hydrochloride) extended-release (ER) tablets (NDA 201655), held by Endo Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355 (Endo). Endo requested that the approval of this application be withdrawn and has waived its opportunity for a hearing.

DATES: Withdrawal of approval is applicable December 23, 2020.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: On June 22, 2006, FDA approved NDA 021610 for OPANA ER (oxymorphone hydrochloride). On December 9, 2011, FDA approved a new formulation of OPANA ER (oxymorphone hydrochloride) tablets, 5 milligrams (mg), 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg, under NDA 201655 (''reformulated OPANA ER'') for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Over the course of 2011 and 2012, Endo removed the original formulation from the market.

Reformulated OPANA ER was intended by the sponsor to be resistant to physical and chemical manipulation for abuse by snorting or injecting. Although the reformulated product met the regulatory standards for approval, FDA determined that the data did not show that product could be expected to

meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for OPANA ER.

Based on postmarketing data, FDA later observed that there was a significant shift in the route of abuse from nasal to injection following the product's reformulation. Injection abuse of reformulated OPANA ER has been associated with a serious outbreak of HIV and hepatitis C, as well as cases of a serious blood disorder (thrombotic microangiopathy). On June 8, 2017, FDA requested that Endo remove reformulated OPANA ER from the market based on its concern that the benefits of the drug may no longer outweigh its risks due to the public health consequences of abuse (see *https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse*). On July 6, 2017, Endo announced it would voluntarily remove reformulated OPANA ER from the market.

On October 3, 2017, Endo requested withdrawal of NDA 201655 for reformulated OPANA ER under § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing. For the reasons discussed above, and pursuant to the applicant's request, approval of NDA 201655 for reformulated OPANA ER (oxymorphone hydrochloride) extended-release tablets, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of reformulated OPANA ER into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: December 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28283 Filed 12–22–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2272]

Hospira, Inc., et al.; Withdrawal of Approval of 27 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 27 new drug applications (NDAs) from multiple applicants. The applicants 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 January 22, 2021.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 008809	M.V.I.-12 Adult (ascorbic acid, biotin, cyanocobalamin, dexpanthenol, ergocalciferol, folic acid, niacinamide, pyridoxine hydrochloride (HCl), riboflavin 5'-phosphate sodium, thiamine HCl, vitamin A, and vitamin E) Injection, 10 milligrams (mg)/milliliters (mL), 0.006 mg/mL, 0.5 micrograms (mcg)/mL, 1.5 mg/mL, 20 International Units (IU)/mL, 0.04 mg/mL, 4 mg/mL, 0.4 mg/mL, 0.36 mg/mL, 0.3 mg/mL, 330 Units/mL, and 1 IU/mL; and 20 mg/mL, 0.006 mg/mL, 0.05 mcg/mL, 1.5 mg/mL, 0.0005 mg/mL, 0.06 mg/mL, 4 mg/mL, 0.6 mg/mL, 0.36 mg/mL, 0.6 mg/mL, 0.1 mg/mL, and 1 mg/mL.	
	M.V.I.-12 Adult (ascorbic acid, biotin, cyanocobalamin, dexpanthenol, ergocalciferol, folic acid, niacinamide, pyridoxine HCl, riboflavin, thiamine HCl, vitamin A, and vitamin E) Injection, 20 mg/mL, 0.006 mg/mL, 0.5 mcg/mL, 1.5 mg/mL, 20 IU/mL, 0.6 mg/mL, 4 mg/mL, 0.4 mg/mL, 0.36 mg/mL, 0.6 mg/mL, 330 Units/mL, and 1 IU/mL..	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045.
NDA 017673	Aminosyn (amino acids) Injection, 5% (5 grams (g)/100 mL), 7% (7 g/100 mL), 7% (pH6) (7 g/100 mL), 8.5% (8.5 g/100 mL), 8.5% (pH6) (8.5 g/100 mL), 10% (10 g/100 mL), and 10% (pH6) (10 g/100 mL).	
	Aminosyn 8.5% With Electrolytes (amino acids, magnesium chloride, potassium chloride, sodium chloride, and sodium phosphate dibasic) Injection, 8.5% (8.5 g/100mL), 102 mg/100 mL, 487 mg/100 mL, 28 mg/100 mL, and 425 mg/100 mL..	
	Aminosyn 8.5% With Electrolytes (amino acids, magnesium chloride, potassium phosphate dibasic, and sodium chloride) Injection, 8.5% (8.5 g/100 mL), 102 mg/100 mL, 522 mg/100 mL, and 410 mg/100 mL..	ICU Medical, Inc., 600 North Field Dr., Lake Forest, IL 60045.
NDA 017735	Modicon 28 (ethinyl estradiol and norethindrone) Tablets, 0.035 mg/0.5 mg	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 017743	Brevicon 28-Day (ethinyl estradiol and norethindrone) Tablets, 0.035 mg/0.5 mg.	Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940.
NDA 017789	Aminosyn 3.5% (amino acids) Injection, 3.5% (3.5 g/100 mL).	
	Aminosyn 3.5% M (amino acids, magnesium acetate, phosphoric acid, potassium acetate, and sodium chloride) Injection, 3.5% (3.5 g/100 mL), 21 mg/100 mL, 40 mg/100 mL, 128 mg/100 mL, and 234 mg/100 mL..	
	Aminosyn 3.5% M (amino acids, magnesium acetate, potassium acetate, and sodium chloride) Injection, 3.5% (3.5 g/100 mL), 21 mg/100 mL, 128 mg/100 mL, and 234 mg/100 mL..	