2. ''This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component. '' (List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.) (§ 558.6(b)(6)(ii)).

3. ''This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component'' (§ 558.6(b)(6)(iii)).

These labeling statements are not subject to review by OMB because, as stated previously, they are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501, *et seq.*).

Based on a review of the information collection since our last request for OMB approval, there has been a significant increase in the number of VFD distributors due to changes to the VFD regulations that were implemented in 2017. Since implementation, the number of approved VFD drugs has increased.

Dated: December 17, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28353 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–2014–N–0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 22, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0167. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Orphan Drugs

OMB Control Number 0910–0167—Revision

This information collection supports FDA regulations implementing sections 525, 526, 527, and 528 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 360aa, 360bb, 360cc, and 360dd), as well as related guidance. Sections 525, 526, 527, and 528 of the FD&C Act pertain to the development of drugs for rare diseases or conditions, including biological products and antibiotics, otherwise known or referred to as ''Orphan Drugs.'' Specifically, section 525 of the FD&C Act requires written recommendations on studies required for approval of a marketing application for a drug for a rare disease or condition. The information collection in 21 CFR 316.10, 316.12, and 316.14 is approved under OMB control numbers 0910–0001 and 0910–0014. Section 526 of the FD&C Act provides for designation of drugs as orphan drugs when certain conditions are met, section 527 provides conditions under which a sponsor of an approved orphan drug enjoys exclusive FDA marketing approval for that drug for the orphan indication for a period of 7 years, and, finally, section 528 is intended to encourage sponsors to make investigational orphan drugs available for treatment of persons in need on an open protocol basis before the drug has been approved for general marketing. Open protocols may permit patients who are not part of the formal clinical investigation to obtain treatment where adequate supplies exist and no alternative effective therapy is available.

We have issued regulations in part 316 (21 CFR part 316) to implement the Orphan Drug provisions of the FD&C Act and to set forth procedures and requirements related to requesting recommendations for investigations of drugs for rare diseases or conditions, requesting designation of a drug for a rare disease or condition, or requesting exclusive approval for a drug for a rare disease or condition. To assist respondents and to be consistent with § 316.50, our Office of Orphan Products Development (OOPD) maintains and makes publicly available guidance documents that apply to the Orphan Drug provisions of the FD&C Act and regulations in part 316. The list is maintained on the internet and guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Accordingly, we are revising the information collection to include Agency guidance. The document entitled ''Meetings with the Office of Orphan Products Development: Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff'' provides recommendations to industry, researchers, patient groups, and other stakeholders interested in requesting a meeting, including a teleconference, with OOPD on issues related to orphan drug designation requests, humanitarian use device designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. It is also intended to assist OOPD staff in addressing such meeting requests. This guidance describes procedures for requesting, preparing, scheduling, conducting, and documenting such meetings and discusses background information we recommend be included in such requests. Information collection attendant to recommendations in the guidance are currently approved under OMB control number 0910–0787; however, for efficiency of Agency operations, we are consolidating it into this related information collection. The guidance is available at *https://www.fda.gov/media/92815/download*.

The FDA Orphan Drug Designation Request Form (Form FDA 4035) is intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from only FDA. The form is a simplified

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