TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
589.2001(f); request for designation	1	1	1	80	80
589.2001(f); response to request for review by FDA	1	1	1	26	26

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

Our estimate of the reporting burden for designation under § 589.2001(f) is based on estimates in the final rule entitled, ''Substances Prohibited From Use in Animal Food or Feed,'' published in the **Federal Register** of April 25, 2008, our experience, and the average number of requests for designation received in the past 3 years. The reporting burden for § 589.2001(f) is minimal because requests for designation are seldom submitted. Since 2009, we have received two requests for designation. In the last 3 years, we have not received any new requests for designation; therefore, we estimate that one or fewer requests for designation will be submitted annually. Although we have not received any new requests for designation in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need of a foreign government to request designation under § 589.2001(f). Table 2, row 1 presents the expected burden of requests for designation. Countries designated under § 589.2001(f) are subject to review by FDA to ensure that their designation remains appropriate. We assume a country's response to a request for review will take about one third the time and effort of a request for designation. Table 2, row 2 presents the expected burden of a request for review. The burden for this information collection has not changed since the last OMB approval.

Dated: October 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23948 Filed 11–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–P–2044]

Determination That REVEX (Nalmefene Hydrochloride Injection), 0.1 Milligram Base/Milliliter and 1.0 Milligram Base/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 REVEX (nalmefene hydrochloride injection), 0.1 milligram (mg) base/milliliter (mL) and 1.0 mg base/mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Kelley Nduom, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6221, Silver Spring, MD 20993–0002, 301–796–8597.

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 (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, 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).

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.

REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, is the subject of NDA 20–459, currently held by West-Ward Pharmaceuticals International Limited, and initially approved on April 17, 1995. REVEX is indicated for the complete or partial reversal of opioid drug effects, including respiratory depression, induced by either natural or synthetic opioids. REVEX is also indicated in the management of known or suspected opioid overdose.

In a letter dated June 5, 2009, Baxter Healthcare Corporation, the NDA holder at the time, notified FDA that the manufacturing and distribution of REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, had been discontinued on May 21, 2008, for business reasons. REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Nirsum Pharmaceuticals, LLC, submitted a citizen petition dated March 31, 2017 (Docket No. FDA–2017–

P–2044), under 21 CFR 10.30, requesting that the Agency determine whether REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition (and comments submitted to the docket) and reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23952 Filed 11–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2017–0109; Control Number: 1625–0030]

Collection of Information Under Review by Office of Management and Budget; OMB

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for reinstatement, without change, of the following collection of information: 1625–0030, Oil and Hazardous Materials Transfer Procedures. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before December 4, 2017.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2017–0109] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email: dhsdeskofficer@omb.eop.gov.*

(2) *Mail:* OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request [USCG–2017–0109], and must be received by December 4, 2017.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).