TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN ¹

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>589.2001(f); request for designation</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>589.2001(f); response to request for review by FDA</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>26</td>
<td>26</td>
</tr>
</tbody>
</table>

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, we have received two requests for designation. In the last 3 years, we have received many 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, 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 proposed 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.

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REVEX (Nalmefene Hydrochloride Injection), 0.1 Milligram Base/Milliliter and 1.0 Milligram Base/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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.

SUPPLEMENTAL 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(f)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(f)(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.

Nirsim Pharmaceuticals, LLC, submitted a citizen petition dated March 31, 2017 (Docket No. FDA–2017–
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: disdeskofficer@omb.eop.gov.
(2) Mail: OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.


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;