We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Controlled Correspondence Related to Generic Drug Development—OMB Control Number 0910–0797—Revision.

Description: FDA has agreed to specific program enhancements and performance goals specified in the GDUFA II Commitment Letter. One of the performance goals applies to controlled correspondence related to generic drug development. The GDUFA II Commitment Letter includes details on FDA's commitment to respond to questions submitted as controlled correspondence within certain time frames. To facilitate FDA's prompt consideration of the controlled correspondence and to assist in meeting the prescribed time frames, FDA recommends including the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number and submission date of any previous, related controlled correspondence that was accepted for substantial review and response, if any, as well as a copy of that previous controlled correspondence and FDA's response, if any; (4) the relevant reference listed drug(s), as applicable, including the application number, proprietary (brand) name, manufacturer, active ingredient, dosage form, and strength(s); (5) a statement that the controlled correspondence is related to a potential abbreviated new drug application (ANDA) submission to the Office of Generic Drugs, and the ANDA number, if applicable; (6) a concise statement of the inquiry; (7) a recommendation of the appropriate FDA review discipline; and (8) relevant prior research and supporting materials.

The GDUFA II Commitment Letter also includes details on FDA's commitment to respond to requests to clarify ambiguities in FDA's controlled correspondence response within certain time frames. To facilitate FDA's prompt consideration of the request, and to assist in meeting the prescribed time frames, FDA recommends including the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number, submission date of the controlled correspondence on which the requestor is seeking clarification, a copy of that previous controlled correspondence, and FDA's response to the controlled correspondence; and (4) the clarifying questions and the corresponding section(s) of FDA's controlled correspondence response on which the requestor is seeking clarification.

The following information is based on inquiries considered controlled correspondence and submitted to FDA for fiscal years 2014, 2015, and 2016. FDA estimates approximately 390 generic drug manufacturers and related industry (*e.g.,* contract research organizations conducting bioanalytical or bioequivalence clinical trials) or their representatives would each submit an average of 3.8 inquiries annually for a total of 1,496 inquiries [1,496 ÷ 390 = 3.8]. Information submitted with each inquiry varies widely in content, depending on the complexity of the request. Inquiries that are defined as controlled correspondence may range from a simple inquiry on generic drug labeling to a more complex inquiry for a formulation assessment for a specific proposed generic drug product. As a result, these inquiries can vary between 1 to 10 burden hours, respectively.

Because the content of inquiries considered controlled correspondence is widely varied, we are providing an average burden hour for each inquiry. We estimate that it will take an average of 5 hours per inquiry for industry to gather necessary information, prepare the request, and submit the request to FDA. As a result, we estimate that it will take an average of 7,480 total hours annually for industry to prepare and submit inquiries considered controlled correspondence.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Submission of controlled correspondence	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Generic drug manufacturers, related industry, and representatives	390	3.8	1,496	5	7,480

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

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: October 30, 2017.

Anna K. Abram,

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

[FR Doc. 2017–23947 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–2011–N–0510]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited From Use in Animal Food or Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information

collection provisions of existing FDA regulations concerning substances prohibited for use in animal food or feed.

DATES: Submit either electronic or written comments on the collection of information by January 2, 2018.

ADDRESSES: You may submit comments as follows: Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 2, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 2, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0510 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited From Use in Animal Food or Feed.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Substances Prohibited From Use in Animal Food or Feed—21 CFR 589.2001

OMB Control Number 0910–0627—Extension

This information collection supports Agency regulations regarding substances prohibited from use in animal food or feed. Bovine spongiform encephalopathy (BSE) is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. Our regulation at § 589.2001 (21 CFR 589.2001) entitled,

''Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy'' is designed to further strengthen existing safeguards against the establishment and amplification of BSE in the United States through animal feed. The regulation prohibits the use of certain cattle origin materials in the food or feed of all animals. These materials are referred to as ''cattle materials prohibited in animal feed'' or CMPAF. Under § 589.2001, no animal feed or feed ingredient can contain CMPAF. As a result, we impose requirements on renderers of specifically defined cattle materials, including reporting and recordkeeping requirements. For purposes of the regulation, we define a renderer as any firm or individual that processes slaughter byproducts, animals unfit for human consumption, including carcasses of dead cattle, or meat scraps. Reporting and recordkeeping requirements are necessary because once materials are separated from an animal it may not be possible, without records, to know whether the cattle material meets the requirements of our regulation.

Recordkeeping: Renderers that receive, manufacture, process, blend, or distribute CMPAF, or products that contain or may contain CMPAF, must take measures to ensure that the materials are not introduced into animal feed, including maintaining adequate written procedures specifying how such processes are to be carried out (§ 589.2001(c)(2)(ii)). Renderers that receive, manufacture, process, blend, or distribute CMPAF, are required to establish and maintain records sufficient to track the CMPAF to ensure that they are not introduced into animal feed (§ 589.2001(c)(2)(vi)).

Renderers that receive, manufacture, process, blend, or distribute *any* cattle materials must establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with, or does not otherwise contain, CMPAF (§ 589.2001(c)(3)(i)).

Renderers that receive, manufacture, process, blend, or distribute *any* cattle materials must, if these materials were obtained from an establishment that segregates CMPAF from other materials, establish and maintain records to demonstrate that the supplier has adequate procedures in place to effectively exclude CMPAF from any materials supplied (§ 589.2001(c)(3)(i)). Records will meet this requirement if they include either: (1) Certification or other documentation from the supplier that materials supplied do not include CMPAF (§ 589.2001(c)(3)(i)(A)) or (2) documentation of another method acceptable to FDA, such as third-party certification (§ 589.2001(c)(3)(i)(B)).

Reporting: Under our regulations, we may designate a country from which cattle materials are not considered CMPAF. Section 589.2001(f) provides that a country seeking to be so designated must send a written request to the Director of the Center for Veterinary Medicine. The information the country is required to submit includes information about that country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the cattle materials from the requesting country do or do not meet the definitions set forth in § 589.2001(b)(1). We use the information to determine whether to grant a request for designation and to impose conditions if a request is granted. Section 589.2001(f) further states that countries designated under that section will be subject to our future review to determine whether their designations remain appropriate. As part of this process, we may ask designated countries from time to time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We may revoke a country's designation if we determine that it is no longer appropriate. Therefore, designated countries may respond to our periodic requests by submitting information to confirm their designations remain appropriate. We use the information to ensure their designations remain appropriate.

Description of Respondents: Respondents to this information collection include rendering facilities, feed manufacturers, livestock feeders, and foreign governments seeking designation under § 589.2001(f).

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
589.2001(c)(2)(ii), maintain written procedures	50	1	50	20	1,000
589.2001(c)(2)(vi) and (c)(3)(i), maintain records	175	1	175	20	3,500
589.2001(c)(3)(i)(A) and (B), certification or documentation from the supplier	175	1	175	26	4,550
Total					9,050

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

Except where otherwise noted, this estimate is based on our estimate of the number of facilities affected by the final rule entitled, ''Substances Prohibited From Use in Animal Food or Feed'', published in the **Federal Register** of April 25, 2008 (73 FR 22720 at 22753). The estimated recordkeeping burden is derived from Agency resources and discussions with affected industry. Our regulations require the maintenance of certain written procedures if cattle not inspected and passed for human consumption are to be rendered for use in animal feed. The recordkeeping burden associated with the requirement to maintain written procedures (§ 589.2001(c)(2)(ii)) will apply to only those renderers that choose to render for use in animal feed cattle not inspected and passed for human consumption. The recordkeeping requirement in § 589.2001(c)(2)(vi) will apply to the limited number of renderers that will handle CMPAF. We estimate that the recordkeeping burden associated with § 589.2001(c)(3)(i) would apply to the balance of the rendering firms not handling CMPAF. Table 1 also reflects the estimated 26 hours each renderer will need to satisfy the requirement in § 589.2001(c)(3)(i)(A) and (B) under which renderers must maintain records from their supplier, certifying that materials provided were free of CMPAF.

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–