

TABLE 1—CERTIFICATES AND USES

Type of certificate	Use
“Supplementary Information Certificate to Foreign Government Requests”.	For the export of products legally marketed in the United States.
“Exporter’s Certification Statement Certificate to Foreign Government”.	
“Exporter’s Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)”.	
“Supplementary Information Certificate of Exportability Requests” .....	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&C Act.
Exporter’s Certification Statement Certificate of Exportability”.....	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license.
“Supplementary Information Certificate of a Pharmaceutical Product” .....	For the export of a non-clinical research use only product, material, or component that is not intended for human use and which may be marketed in, and legally exported from the United States under the FD&C Act.
“Exporter’s Certification Statement Certificate of a Pharmaceutical Product”..	
“Supplementary Information Non-Clinical Research Use Only Certificate”.	
“Exporter’s Certification Statement (Non-Clinical Research Use Only)”	

Appropriate centers within FDA review product information submitted by firms in support of the firms’ certificate requests. We rely on respondents to certify their compliance with all applicable requirements of the FD&C Act both at the time the certification request is submitted to FDA and at the time the certification is submitted to the respective foreign government. Information regarding FDA’s Export Certificates may be found on our website at <https://www.fda.gov/>

*regulatory-information/search-fda-guidance-documents/fda-export-certificates.*

On September 16, 2020, we submitted an information collection request to the Office of Management and Budget (OMB) to revise certain data elements as may be applicable under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Because Section 3856 of the CARES Act contained immediately effective provisions obligating FDA to review and

process certification requests, we requested emergency processing by OMB under 5 CFR 1320.13 for the respective information collection. Our information collection request was granted by OMB on September 29, 2020. Therefore, in accordance with 5 CFR 1320.8(d)(1), we invite comment on the burden we attribute to the information collection, which we estimate as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

FDA center	Number of Respondents	Number of Responses per Respondent	Total Annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research .....	2,651	1	2,651	1	2,651
Center for Devices and Radiological Health .....	11,175	1	11,175	2	22,350
Center for Drug Evaluation and Research .....	3,680	1	3,680	1	3,680
Center for Veterinary Medicine .....	1,925	1	1,925	1	1,925
<b>Total .....</b>	.....	.....	.....	.....	<b>30,606</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on our current evaluation of the information collection, we have made no adjustments since our last request for OMB review and approval.

Dated: December 14, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020-28064 Filed 12-18-20; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2020-N-2217]**

**Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Use**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) 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 reporting and recordkeeping requirements of our regulations concerning new animal drugs for investigational use.

**DATES:** Submit either electronic or written comments on the collection of information by February 19, 2021.

**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 February 19, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 19, 2021. 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-2020-N-2217 for "New Animal Drugs for Investigational Use." 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, 240-402-7500.

• **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.govinfo.gov/content/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, 240-402-7500.

**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](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), 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.

#### **New Animal Drugs for Investigational Use—21 CFR Part 511**

#### **OMB Control Number 0910-0117—Extension**

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to approve new animal drugs. A new animal drug application (NADA) cannot be approved until, among other things, the new animal drug has been demonstrated to be safe and effective for its intended use(s). In order to properly test a new animal drug for an intended use, appropriate scientific investigations must be conducted. Under specific circumstances, section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) permits the use of an investigational new animal drug to generate data to support a NADA approval. Section 512(j) of the FD&C Act authorizes us to issue regulations relating to the investigational use of new animal drugs.

Our regulations in part 511 (21 CFR part 511) set forth the conditions for investigational use of new animal drugs and require reporting and recordkeeping. The information collected is necessary to protect the

public health. We use the information to determine that investigational animal drugs are distributed only to qualified investigators, adequate drug accountability records are maintained, and edible food products from treated food-producing animals are safe for human consumption. We also use the information collected to monitor the validity of the studies submitted to us to support new animal drug approval.

**Reporting:** Our regulations require that certain information be submitted to us in a “Notice of Claimed Investigational Exemption for a New Animal Drug” (NCIE) to qualify for the exemption and to control shipment of the new animal drug and prevent potential abuse. The NCIE must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals (§ 511.1(b)(4) (21 CFR 511.1(b)(4))). If the new animal drug is to be used in food-producing animals (e.g., cattle,

swine, chickens, fish, etc.), certain data must be submitted to us to obtain authorization for the use of edible food products from treated food-producing animals (§ 511.1(b)(5)). We require sponsors upon request to submit information with respect to the investigation to determine whether there are grounds for terminating the exemption (§ 511.1(b)(6)). We require sponsors to report findings that may suggest significant hazards pertinent to the safety of the new animal drug (§ 511.1(b)(8)(ii)). We also require reporting by importers of investigational new animal drugs for clinical investigational use in animals (§ 511.1(b)(9)). The information provided by the sponsor in the NCIE is needed to help ensure that the proposed investigational use of the new animal drug is safe and that any edible food will not be distributed without proper authorization from FDA. Information contained in an NCIE submission is monitored under our Bioresearch Monitoring Program. This program permits us to monitor the validity of the studies and to help ensure the proper use of the drugs is maintained by the investigators.

**Recordkeeping:** If the new animal drug is only for tests in vitro or in laboratory research animals, the person

distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery (§ 511.1(a)(3) and (b)(3)). We require complete records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug (§ 511.1(b)(7)). We also require records of all reports received by a sponsor from investigators to be retained for 2 years after the termination of an investigational exemption or approval of a new animal drug application (§ 511.1(b)(8)(i)).

**Description of Respondents:** Respondents to this collection of information are persons who use new animal drugs for investigational purposes. Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities, as well as research firms and members of the medical professions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
511.1(b)(4); submission of NCIE .....	279	5.94	1,657	1	1,657
511.1(b)(5); submission of data to obtain authorization for the use of edible food products .....	279	0.10	28	8	224
511.1(b)(6); submission of any additional information upon request of FDA .....	279	.001	0.28	1	0.28
511.1(b)(8)(ii); reporting of findings that may suggest significant hazards pertinent to the safety of the new animal drug .....	279	0.05	14	2	28
511.1(b)(9); reporting by importers of investigational new animal drugs for clinical investigational use in animals .....	279	0.05	14	8	112
<b>Total .....</b>			<b>1,713</b>		<b>2,021</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR section/activity	No. of record-keepers	No. of records per record-keeper	Total annual records	Average burden per recordkeeping	Total hours
511.1(a)(3); maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery .....	279	0.99	276	1	276
511.1(b)(3); maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug or feed containing same is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery .....	279	5.94	1,657	1	1,657

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>—Continued

21 CFR section/activity	No. of record-keepers	No. of records per record-keeper	Total annual records	Average burden per recordkeeping	Total hours
511.1(b)(7); maintain records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug .....	279	5.94	1,657	3.5	5,800
511.1(b)(8)(i); maintain records of all reports received by a sponsor from investigators .....	279	5.94	1,657	3.5	5,800
<b>Total .....</b>			<b>5,247</b>		<b>13,533</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on our informal communication with industry. Based on the number of sponsors subject to animal drug user fees, we estimate that there are 279 respondents. We use this estimate consistently throughout the table and calculate the “number of responses per respondent” by dividing the total annual responses by number of respondents. We note an apparent difference in the estimated number of respondents from the previous renewal issued in 2018. There was an error in calculating the number of sponsors subject to animal drug user fees in the 2018 renewal. When calculating the number of recordkeepers, we inadvertently used the number of sponsors that paid user fees (*i.e.*, those that did not qualify for user fee waivers) as opposed to the total number of sponsors subject to animal drug user fees. Both fee-paying and non-fee-paying sponsors are respondents with respect to this information collection.

Additional information needed to make a final calculation of the total burden hours (*i.e.*, the number of respondents, the number of recordkeepers, the number of NCIEs received, etc.) is derived from our records. There is a small increase in the total burden hours which we attribute to an increase in the number of annual responses and records.

Dated: December 14, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020-28068 Filed 12-18-20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-P-1650]

#### Determination That DOBUTREX (Dobutamine Hydrochloride), Equivalent 12.5 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 DOBUTREX (dobutamine hydrochloride), equivalent (eq) 12.5 milligram (mg) base/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

#### FOR FURTHER INFORMATION CONTACT:

Jessica Tierney, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993-0002, 301-796-9120, [Jessica.Tierney@fda.hhs.gov](mailto:Jessica.Tierney@fda.hhs.gov).

**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, drugs are 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.

DOBUTREX (dobutamine hydrochloride), eq 12.5 mg base/mL, is the subject of NDA 017820, held by Eli Lilly and Co., and initially approved on July 18, 1978. DOBUTREX (dobutamine hydrochloride), eq 12.5 mg base/mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Cardinal Health submitted a citizen petition dated July 9, 2020 (Docket No. FDA-2020-P-1650), under 21 CFR 10.30, requesting that the Agency determine whether DOBUTREX