

FDA 2915 entitled “Radioactive Drug Research Committee Report on Research Use of Radioactive Drugs Study Summary.”

Under § 361.1(d)(5), each investigator will obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant or, based on a pregnancy test, be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator will immediately report to the RDRC all adverse effects associated with use of the drug, and the committee will then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they

are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under the regulations are also specified and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (*i.e.*, to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application under 21 CFR part 312, and the associated information collections are covered in OMB control number 0910–0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required

regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks. Respondents to this information collection are the chairperson or chairpersons of each individual RDRC, investigators, and participants in the studies. The burden estimates are based on our experience with these reporting and recordkeeping requirements and the number of submissions we received under the regulations over the past 3 years.

In the **Federal Register** of January 21, 2020 (85 FR 3390), we 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 2}

21 CFR section and applicable form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 361.1(c)(3) reports and (c)(4) approval (Form FDA 2914: Membership Summary) ³ .	62	1	62	1	62
§ 361.1(c)(3) reports (Form FDA 2915: Study Summary) ⁴ .	40	10	434	3.5	1,519
§ 361.1(d)(8) adverse events	10	1	10	.5 (30 minutes)	5
Total	506	1,586

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

² Numbers may not sum due to rounding.

³ <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM094979.pdf>.

⁴ <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074720.pdf>.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN^{1 2}

21 CFR section	Number of recordkeepers	Number of records per recordkeepers	Total annual responses	Average burden per recordkeeping	Total hours
§ 361.1(c)(2) RDRC	62	4	248	10	2,480
§ 361.1(d)(5) human research subjects	40	10	434	.75 (45 minutes) ..	326
Total	682	2,806

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

² Numbers may not sum due to rounding.

We have adjusted our estimate for the information collection to reflect an annual decrease of 525 hours and 147 responses since last OMB review. This adjustment corresponds to fewer submissions we have received under the information collection over the last few years.

Dated: June 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14262 Filed 7–1–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0588]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exceptions or Alternatives To Labeling Requirements for Products Held by the Strategic National Stockpile

AGENCY: Food and Drug Administration, Health and Human Services (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 requirements related to the exceptions or alternatives to labeling requirements for products held by the Strategic National Stockpile (SNS).

DATES: Submit either electronic or written comments on the collection of information by August 31, 2020.

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 August 31, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 31, 2020. 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-2010-N-0588 for "Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile." 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:

Domini Bean, Office of Operations, Food and Drug Administration, Three

White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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.

Exceptions or Alternatives To Labeling Requirements for Products Held by the Strategic National Stockpile

OMB Control Number 0910-0614—*Extension*

Under the Public Health Service Act (PHS Act), the Department of Health and Human Services stockpiles medical products that are essential to the health security of the Nation (see 42 U.S.C. 247d-6b). This collection of medical products for use during national health emergencies, known as the SNS, is to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a

bioterrorist attack or other public health emergency.

It may be appropriate for certain medical products that are or will be held in the SNS to be labeled in a manner that would not comply with certain FDA labeling regulations given their anticipated circumstances of use in an emergency. However, noncompliance with these labeling requirements could render such products misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

Under 21 CFR 201.26, 610.68, 801.128, and 809.11 (§§ 201.26, 610.68, 801.128, and 809.11), the appropriate FDA Center Director may grant a request for an exception or alternative to certain regulatory provisions pertaining to the labeling of human drugs, biological products, medical devices, and in vitro diagnostics that currently are or will be included in the SNS if certain criteria are met. The appropriate FDA Center Director may grant an exception or alternative to certain FDA labeling requirements if compliance with these labeling requirements could adversely affect the safety, effectiveness, or availability of products that are or will be included in the SNS. An exception or alternative granted under the regulations may include conditions or safeguards so that the labeling for such products includes appropriate information necessary for the safe and effective use of the product given the product's anticipated circumstances of use. Any grant of an exception or alternative will only apply to the specified lots, batches, or other units of medical products in the request. The appropriate FDA Center Director may also grant an exception or alternative to the labeling provisions specified in the regulations on his or her own initiative.

Under §§ 201.26(b)(1)(i) (human drug products), 610.68(b)(1)(i) (biological products), 801.128(b)(1)(i) (medical devices), and 809.11(b)(1)(i) (in vitro diagnostic products for human use) an SNS official or any entity that manufactures (including labeling,

packing, relabeling, or repackaging), distributes, or stores such products that are or will be included in the SNS may submit, with written concurrence from a SNS official, a written request for an exception or alternative to certain labeling requirements to the appropriate FDA Center Director. Except when initiated by an FDA Center Director, a request for an exception or alternative must be in writing and must:

- Identify the specified lots, batches, or other units of the affected product;
- identify the specific labeling provisions under the regulations that are the subject of the request;
- explain why compliance with the specified labeling provisions could adversely affect the safety, effectiveness, or availability of the product subject to the request;
- describe any proposed safeguards or conditions that will be implemented so that the labeling of the product includes appropriate information necessary for the safe and effective use of the product given the anticipated circumstances of use of the product;
- provide copies of the proposed labeling of the specified lots, batches or other units of the affected product that will be subject to the exception or alternative; and
- provide any other information requested by the FDA Center Director in support of the request.

If the request is granted, the manufacturer may need to report to FDA any resulting changes to the new drug application, biologics license application, premarket approval application, or premarket notification (510(k)) in effect, if any. The submission and grant of an exception or an alternative to the labeling requirements specified in the regulations may be used to satisfy certain reporting obligations relating to changes to product applications under §§ 314.70, 601.12, 814.39, and 807.81 (21 CFR 314.70 (human drugs), 21 CFR 601.12 (biological products), 21 CFR 814.39 (medical devices subject to premarket

approval), or 21 CFR 807.81 (medical devices subject to 510(k) clearance requirements)). The information collection provisions in §§ 314.70, 601.12, 807.81, and 814.39 have been approved under OMB control numbers 0910-0001, 0910-0338, 0910-0120, and 0910-0231 respectively. On a case-by-case basis, the appropriate FDA Center Director may also determine when an exception or alternative is granted that certain safeguards and conditions are appropriate, such as additional labeling on the SNS products, so that the labeling of such products would include information needed for safe and effective use under the anticipated circumstances of use.

Respondents to this collection of information are entities that manufacture (including labeling, packing, relabeling, or repackaging), distribute or store affected SNS products. Based on data from fiscal years 2017, 2018, and 2019, FDA estimates an average of one request annually for an exception or alternative received by FDA. FDA estimates an average of 24 hours preparing each request. The average burden per response for each submission is based on the estimated time that it takes to prepare a supplement to an application, which may be considered similar to a request for an exception or alternative. To the extent that labeling changes not already required by FDA regulations are made in connection with an exception or alternative granted under the regulations, FDA is estimating one occurrence annually in the event FDA would require any additional labeling changes not already covered by FDA regulations. FDA estimates 8 hours to develop and revise the labeling to make such changes. The average burden per response for each submission is based on the estimated time to develop and revise the labeling to make such changes.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	1	1	1	24	24
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	1	1	1	8	8
Total					32

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

Consistent with the PRA, our current estimate of the burden of the information collection is based on our evaluation over the past 3 years. However, in light of recent consumption of products from the SNS, we expect future adjustments may be necessary and invite specific comment in this regard.

Dated: June 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0145]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Associated With Animal Drug and Animal Generic Drug User Fees

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 August 3, 2020.

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 0910-0540. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@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.

Reporting Associated With Animal Drug and Animal Generic Drug User Fees—21 U.S.C. 379j-12 and 379j-21

OMB Control Numbers 0910-0540—Extension

This information collection supports FDA’s animal drug and animal generic drug user fee programs. The Animal Drug User Fee Act of 2003 (ADUFA) (Pub. L. 108-130) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 740 of the FD&C Act (21 U.S.C. 379j-12), which requires that FDA assess and collect user fees with respect to new animal drug applications for certain applications, products, establishments, and sponsors. It also requires the Agency to grant a waiver from, or a reduction of, those fees in certain circumstances. The Animal Generic Drug User Fee Act of 2008 (AGDUFA) (Pub. L. 110-316) added section 741 of the FD&C Act (21 U.S.C. 379j-21), which establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). On August 14, 2018, H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, was signed into law to reauthorize the ADUFA and AGDUFA programs administered by FDA.

Sponsors of new animal drug applications prepare and submit user fee cover sheets. The Animal Drug User Fee cover sheet (Form FDA 3546) is designed to collect the minimum necessary information to determine whether a fee is required for the review of an application or supplement or whether an application fee waiver was granted, to determine the amount of the fee required, and to ensure that each animal drug user fee payment is appropriately linked to the animal drug application for which payment is made. The form, when completed electronically, results in the generation of a unique payment identification number used by FDA to track the payment. The information collected is used by FDA’s Center for Veterinary Medicine (CVM) to initiate the administrative screening of new animal drug applications and supplements. The information collection associated with the Animal Drug User Fee cover sheet

currently is approved under OMB control number 0910-0539.

Sponsors of abbreviated new animal drug applications also prepare and submit user fee cover sheets. The Animal Generic Drug User Fee cover sheet (Form FDA 3728) similarly is designed to collect the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to ensure that each animal generic drug user fee payment is appropriately linked to the abbreviated new animal drug application for which payment is made. The form, when completed electronically, results in the generation of a unique payment identification number used by FDA to track the payment. The information collected is used by CVM to initiate the administrative screening of abbreviated new animal drug applications. The information collection associated with the Animal Generic Drug User Fee cover sheet currently is approved under OMB control number 0910-0632.

FDA has also developed a guidance for industry (GFI) #170 entitled “Animal Drug User Fees and Fee Waivers and Reductions.” This guidance provides guidance on the types of fees FDA is authorized to collect under section 740 of the FD&C Act, and how to request waivers and reductions from these fees. Further, this guidance also describes what information FDA recommends be submitted in support of a request for a fee waiver or reduction; how to submit such a request; and FDA’s process for reviewing requests. FDA uses the information submitted by respondents to determine whether to grant the requested fee waiver or reduction. The information collection associated with GFI #170 currently is approved under OMB control number 0910-0540.

The information collection provisions approved under OMB control numbers 0910-0539, 0910-0540, and 0910-0632 are similar in that they support FDA’s animal drug and animal generic drug user fee programs. Thus, with this notice, FDA proposes to consolidate these collections of information into one OMB control number for government efficiency and to allow the public to look to one OMB control number for all reporting associated with FDA’s animal drug and animal generic drug user fee programs. Because we are proposing to combine all reporting associated with FDA’s animal drug user fees into one collection, we are consolidating the burden under OMB control number 0910-0540 and discontinuing OMB control numbers 0910-0539 and 0910-0632.