TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					143

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

Table 1 summarizes the total annual burden hours estimated for this information collection. There is no cost to participants other than their time. The total estimated annualized burden hours are 143. A total of approximately 350 trainees will be invited to participate in the web survey. Burden hours were estimated based on experience with prior similar survey activities and information obtained from informal testing by contractor staff.

Dated: December 31, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00039 Filed 1–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0597]

Agency Information Collection Activities; Proposed Collection; Comment Request; Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

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 our regulations related to public index listing of legally marketed unapproved new animal drugs for minor species of animals.

DATES: Submit either electronic or written comments on the collection of information by March 9, 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 March 9, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 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–0597 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.'' 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.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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species—21 CFR Part 516

OMB Control Number 0910–0620—Extension

The Minor Use and Minor Species Animal Health Act of 2004 (the MUMS Act) (Pub. L. 108–282) added section 572 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ccc–1), which authorizes FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats). In enacting the MUMS Act, Congress sought to encourage the development of these new animal drugs. Congress recognized that the markets for drugs intended to treat these species are so small that there are often insufficient economic incentives to motivate drug companies to develop data to support approvals. Further, Congress recognized that some minor species populations are too small or their management systems too diverse to make it practical to conduct traditional studies to demonstrate safety and effectiveness of animal drugs for such uses. As a result of these limitations, drug companies have generally not been willing or able to collect data to support legal marketing of drugs for these species. Consequently, Congress enacted the MUMS Act to provide incentives to develop new animal drugs for minor species, while still ensuring appropriate safeguards for animal and human health. Section 572 of the FD&C Act provides for a public index listing of legally marketed unapproved new animal drugs for minor species. FDA regulations in part 516 (21 CFR part 516) specify, among other things, the criteria and procedures for requesting eligibility for indexing and for requesting addition to the index, as well as the annual reporting requirements for index holders. The administrative procedures and criteria for indexing a new animal drug for use in a minor species are set forth in §§ 516.111 through 516.171. Section 516.165 sets forth the annual reporting requirements for index holders. FDA needs the information to determine: (1) The eligibility of a new animal drug for indexing; (2) that a qualified expert panel proposed to review certain information regarding the new animal drug meets the selection criteria listed in the regulations; (3) whether the Agency agrees with the recommendation of a qualified expert panel that a drug be added to the index; and (4) whether there may be grounds for removing a drug from the index.

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

TABLE 1—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
516.119; requires a foreign drug company to submit and update the name and address of a permanent U.S. resident agent	5	1	5	1	5
516.121; written request for a meeting with FDA to discuss the requirements for indexing a new animal drug	30	2	60	4	240
516.123; written request for an informal conference and a requestor's written response to an FDA initial decision denying a request	3	1	3	8	24
516.125; correspondence and information associated with investigational use of new animal drugs intended for indexing	2	3	6	20	120
516.129; content and format of a request for determination of eligibility for indexing	30	2	60	20	1,200
516.141; information to be submitted to FDA by a requestor seeking to establish a qualified expert panel	20	1	20	16	320
516.143; content and format of the written report of the qualified expert panel	20	1	20	120	2,400
516.145; content and format of a request for addition to the Index	20	1	20	20	400

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.161; content and format of a request for modification of an indexed drug	3	1	3	4	12
516.163; information to be contained in a request to FDA to transfer ownership of a drug's index file to another person	1	1	1	2	2
516.165; requires drug experience reports and distributor statements to be submitted to FDA	10	10	100	5	500
Total					5,223

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

TABLE 2—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
516.141, requires the qualified expert panel leader to maintain a copy of the written report and all notes or minutes relating to panel deliberations that are submitted to the requestor for 2 years after the report is submitted.	30	2	60	0.5 (30 minutes)	30
516.165, requires the holder of an indexed drug to maintain records of all information pertinent to the safety or effectiveness of the indexed drug, from foreign and domestic sources.	10	2	20	1	20
Total					50

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

We based our estimates in tables 1 and 2 on our experience with the MUMS indexing program and the requests for eligibility for indexing and for addition to the index, as well as the periodic drug experience reports submitted during the past 3 years.

Our estimated burden for the information collection reflects an overall increase of 351 reporting hours and a corresponding increase of 85 responses. We attribute this adjustment, generally, to an increase in the number of submissions we received over the last few years. We also reduced our burden hour estimate for drug experience reports and distributor statements under § 516.165 from 8 hours per submission to 5 hours per submission based on our experience with this type of reporting.

Dated: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00042 Filed 1–6–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5971]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recommendations To Reduce the Risk of Transfusion-Transmitted of Infection in Whole Blood and Blood Components; Agency Guidance

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 (the 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 concerning establishment notification of a consignee and consignee notification of a recipient's physician of record regarding a possible increased risk of transfusion-transmitted infection.

DATES: Submit either electronic or written comments on the collection of information by March 9, 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 March 9, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 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,