include certain information and how respondents should notify FDA of a permanent discontinuance or interruption of supply of infant formula.

Section 424(b) of the FD&C Act requires a manufacturer of a critical food to develop, maintain, and implement a redundancy risk management plan that identifies and evaluates risks to the supply of the food for each establishment in which a critical food is manufactured. A risk management plan may identify and evaluate risks to the supply of more than one critical food manufactured at the same establishment. A risk management plan may also identify mechanisms by which the manufacturer would mitigate the impacts of a supply disruption through alternative production sites, alternative suppliers, stockpiling of inventory, or other means. Records of a risk management plan are subject to FDA inspection and copying.

Description of Respondents: Respondents to this information collection are manufacturers of critical foods.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; section 424(a)(1) of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification of a permanent discontinuance or an interruption of the manufacture of a critical food	8	1	8	2	16

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

The estimates in table 1 are based on our experience with similar notification programs. We estimate that each year 5 manufacturers of infant formula will submit notifications in compliance with section 424(a)(1) of the FD&C Act and following recommendations found in the draft guidance. We also estimate that each year 3 manufacturers of medical foods will submit notifications in compliance with section 424(a)(1) of the FD&C Act, for a total of 8 manufacturers of a critical food. We estimate that each manufacturer will submit 1 notification for 8 total annual notifications (8 manufacturers × 1 notification). Each submission will take an estimated 2 hours to complete for an annual reporting burden of 16 hours (8 notifications × 2 hours).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; section 424(b) of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Risk management plan	11	1	11	60	660

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

The estimates in table 2 are based on our experience with similar risk management programs. We estimate that each year 11 manufacturers of critical foods will create and maintain a risk management plan in compliance with section 424(b) of the FD&C Act. We estimate that each risk management plan will take an estimated 60 hours to create and maintain for an annual recordkeeping burden of 660 hours (11 records × 60 hours).

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/guidance-documents-regulatory-information-topic-food-and-dietary-supplements*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: November 26, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28230 Filed 12–2–24; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1993–D–0285]

Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft revised guidance for industry (GFI) #49 entitled ''Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis.'' This draft guidance provides recommendations and considerations for bovine mastitis drug products with antibacterial activity that are administered by intramammary infusion.

DATES: Submit either electronic or written comments on the draft guidance by February 3, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–1993–D–0285 for ''Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paulette Salmon, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6556, *pauline.salmon@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft revised GFI #49 entitled ''Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis.'' This draft guidance replaces final GFI #49, issued in April 1996 entitled ''Target Animal Safety And Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products (Lactating and Non-Lactating Cow Products).'' This draft guidance provides recommendations and considerations for bovine mastitis drug products with antibacterial activity that are administered by intramammary infusion. However, this guidance may also be applicable to mastitis products administered by other routes or to products using other technologies (including those with non-antibacterial mechanisms of action).

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 514 have been approved under OMB control number 0910–0032; 21 CFR 511.1 have been approved under OMB control number 0910–0117.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 25, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28362 Filed 12–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which