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
10.19—request for waiver, suspension, or modification of requirements.	7	1	7	1	7
10.30 and 10.31—citizen petitions and petitions related to ANDAs certain NDAs,[2] or certain BLAs[3].	200	1	200	24	4,800
10.33—administrative reconsideration of action	9	1	9	10	90
10.35—administrative stay of action	12	1	12	10	120
10.65—meetings and correspondence	37	1	37	5	185
10.85—requests for Advisory opinions	1	1	1	16	16
10.115(f)(3)—submitting draft guidance proposals	26	1	26	4	104
12.22—Filing objections and requests for a hearing on a regulation or order.	18	1	18	20	360
12.45—Notice of participation	5	1	5	3	15
External requests for FDA speakers	3,900	1	3,900	0.17 (10 minutes)	663
Total			4,215		6,360

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] New drug applications.
[3] Biologics license applications.

Based on submissions to FDA's Division of Dockets Management since our last evaluation of the information collection, we have made adjustments to burden estimates associated with the individual activities that correspond to the applicable provisions.

We have also added 3,900 responses and 663 hours, annually, to reflect burden we believe is associated with requests to FDA for speaker participation at an external Agency event, assuming an average burden of 10 minutes for each request. As a result of these adjustments, the information collection reflects an annual increase in responses of 3,119 and an annual decrease in hours of 3,360.

Dated: June 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12523 Filed 6–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0598]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles

AGENCY: Food and Drug Administration, 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 July 12, 2023.

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 0910–0154. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@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.

Current Good Manufacturing Practice Regulations for Type A Medicated Articles—21 CFR Part 226

OMB Control Number 0910–0154—Extension

This information collection supports the implementation of FDA statutory and regulatory requirements that govern current good manufacturing practice (cGMP) for Type A medicated articles. A Type A medicated article is an animal feed product containing a concentrated drug diluted with a feed carrier substance. A Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency. Section 501 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351), governs current cGMP for drugs, including Type A medicated articles, and these statutory requirements are codified in part 226 (21 CFR part 226).

Manufacturers are required to establish, maintain, and retain records for Type A medicated articles including records to document procedures required under the manufacturing process to assure that proper quality control is maintained under part 226. Type A medicated articles, which are not manufactured in accordance with these regulations, are considered adulterated under section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)).

Description of Respondents: The respondents to this information collection are manufacturers of Type A medicated articles.

In the **Federal Register** of January 31, 2023 (88 FR 6281), FDA 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 RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
226.42, 226.58, 226.80, 226.102, 226.110, and 226.115; Recordkeeping and maintenance of records for components used in the manufacture of the medicated premixes, laboratory controls, packaging and labeling, master formula and batch-production, distribution records and complaint files.	65	1,370	89,050	~1 hour	89,050

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

The burden we attribute to recordkeeping activities associated with the provisions in 21 CFR part 226 are assumed to be distributed among the individual elements and averaged among respondents. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12512 Filed 6–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–3011]

Luis Anarbol Moran: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Luis Anarbol Moran for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Moran was convicted of one felony count under Federal law for smuggling goods into the United States. The factual basis supporting Mr. Moran's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Moran was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of March 30, 2023 (30 days after receipt of the notice), Mr. Moran had not responded. Mr. Moran's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable June 12, 2023.

ADDRESSES: Any application by Mr. Moran for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2022–N–3011. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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 application 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, 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 between 9 a.m.