pulverized roots of cynanchum auriculatum, in addition to aegeline, in its OxyElite Pro ''Advanced Formula'' supplement. The cynanchum auriculatum-containing product was called OxyElite Pro ''Advanced Formula.'' On or about June 15, 2013, Mr. Geissler's coconspirator instructed a Chinese chemical seller to have two metric tons of ground cynanchum auriculatum root powder, rather than an extract, shipped internationally to laboratories in California for inclusion in USP Labs' products, using the false name ''cynanchum auriculatum root extract.'' USP Labs then used the substance in its OxyElite Pro ''Advanced Formula'' supplement which it shipped to retailers and wholesalers using false labels. When there was a liver-injury outbreak, USP Labs put out a misleading press release stating that the ingredients in OxyElite Pro had been studied and showed ''no negative liver issues,'' but USP Labs knew that a study had shown ''liver issues'' related to cynanchum auriculatum. Mr. Geissler did, with intent to defraud and mislead, cause the shipment of misbranded OxyElite Pro ''Advanced Formula'' to be shipped in interstate commerce. The conspirators collected millions in revenue.

As a result of this conviction FDA sent Mr. Geissler, by certified mail on March 4, 2021, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Geissler's felony conviction of conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 21 U.S.C. 333(a)(2)), constitutes conduct relating to the importation of an article of food into the United States because the offense involved a conspiracy with others to import a variety of chemicals with false labeling in order to either use those chemicals in dietary supplements which would themselves also contain false labeling or to determine whether those chemicals could be used in new dietary supplements.

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Geissler should be subject to a 5-year period of debarment. The proposal also offered Mr. Geissler an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised Mr. Geissler that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Geissler failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Jacobo Geissler has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Geissler is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective July 28, 2021. Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Jacobo Geissler is a prohibited act.

Any application by Mr. Geissler for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2020–N–2169 and sent to the Dockets Management Staff (**ADDRESSSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: July 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16045 Filed 7–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6730]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Reporting

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 27, 2021.

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 0910–0437. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Reporting—21 CFR Part 803

OMB Control Number 0910–0437—Extension

This information collection supports FDA regulations and FDA's Medical Device Reporting program. Section 519(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(a), (b), and (c)) requires user facilities, manufacturers, importers, and distributors of medical devices to report adverse events involving medical

devices to FDA. These provisions are codified in part 803 (21 CFR part 803), Medical Device Reporting. As amended most recently by the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52), medical device manufacturers and importers must submit medical device reports (MDRs) using FDA's electronic submission system. User facilities, however, may elect to submit reports using paper-based Form FDA 3500A—MedWatch—Mandatory Reporting (approved under OMB control number 0910–0291). The regulations also establish recordkeeping requirements and provide for certain exemptions, variances, or alternative forms of reporting. Exemptions and/or variances from individual reporting must be requested in writing and must receive Agency approval. Additionally, the regulations permit user facilities to submit paper-based annual reports, for which we have developed Form FDA 3419 entitled ''Medical Device Reporting Annual User Facility Report.''

This information collection also includes the use of existing formats such as Form FDA 3500A [1]—MedWatch—Mandatory Reporting to allow manufacturers to summarize in a single report multiple events with shared characteristics for device associated reportable malfunction events. For example, the Voluntary Malfunction Summary Reporting Program (VMSRP) [2] provides recommendations for manufacturers of certain devices to submit a single report that summarizes multiple device associated reportable malfunction events on a quarterly basis. The VMSRP was established under section 519(a)(1)(B)(ii) of the FD&C Act and reflects goals for streamlining malfunction reporting as outlined in the Medical Device User Fee Amendments (MDUFA) IV ''Commitment Letter'' for 2018 through 2022 agreed to by FDA and industry and submitted to Congress. The Commitment Letter was finalized with the passage of FDARA on August 18, 2017, and, as passed, is entitled ''MDUFA Performance Goals And Procedures, Fiscal Years 2018 Through 2022.'' [3]

The information that is obtained from this information collection will be used to evaluate risks associated with medical devices and enable FDA to take appropriate measures to protect the public health. Complete, accurate, and timely adverse event information is necessary for the identification of emerging device problems so the Agency can protect the public health under section 519 of the FD&C Act. FDA makes the releasable information available to the public for downloading on its website. Respondents are manufacturers and importers of medical devices and device user facilities.[4]

In the **Federal Register** of April 29, 2021 (86 FR 22671), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. Upon our own review, however, we have updated submission figures from our VMSRP program and supplemental reports under § 803.56 (21 CFR 803.56) to reflect an increase in submissions. Since publication of our 60-day notice, therefore, we have modified our estimated burden for collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Exemptions/Variances—803.19		6	135.8	815	0.10 (6 minutes).	82
User Facility Reporting—803.30 and 803.32.		271	17.2	4,661	0.35 (21 minutes).	1,631
User Facility Annual Reporting—803.33	3,419	93	2	186	1	186
Importer Reporting, Death and Serious Injury—803.40 and 803.42.		112	440.25	49,308	0.10 (6 minutes).	4,931
Manufacturer Reporting—803.50, 803.52 and 803.53.		1,799	809.83	1,456,884	0.10 (6 minutes).	145,688
Voluntary Malfunction Summary Reporting Program.		67	695.15	46,575	0.10 (6 minutes).	4,658
Supplemental Reports—803.56		1,291	438	565,458	0.10 (6 minutes).	56,546
Total						213,722

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

The number of respondents to the information collection is based on MDRs received by FDA recently. The annual frequency per response and total annual responses shown are based on the number of MDRs reported during the same period. Based on the scope and conditions of the VMSRP and our experience with MDR reporting, FDA estimates that approximately 10 percent of malfunction reports would continue to be submitted as individual reports. Approximately 62 percent of the manufacturer reports received under §§ 803.50, 803.52 and 803.53 are malfunction reports (903,268 of the 1,456,884 total annual responses received in 2020).

Supplemental Reports—§ 803.56. We have increased our estimate, of the number of supplemental reports to reflect a corresponding increase of annual submissions, as reflected in table 1, row 7.

Voluntary Malfunction Summary Reporting Program. The VMSRP includes the same respondent pool as individual manufacturer reporting. Based on a current review of Agency data, we have increased our estimate to

[1] Form FDA 3500A is approved under OMB control number 0910–0291.

[2] In the **Federal Register** of August 17, 2018 (83 FR 40973), FDA issued a notification permitting manufacturers to report certain device malfunction MDRs in summary form on a quarterly basis.

[3] Available at: *https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.*

[4] Device user facility means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in § 803.3 (21 CFR 803.3), which is not a physician's office (also defined in § 803.3).

reflect an increase in annual submissions, as reflected in table 1, row 6.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
MDR Procedures—803.17	1,799	1	1,799	3.3	5,937
MDR Files—803.18	1,799	1	1,799	1.5	2,699
Total					8,636

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

The number of respondents in table 2 is based on the MDRs reported to FDA's internal databases recently. We believe that the majority of respondents (manufacturers, user facilities, and importers) have already established written procedures and MDR files to document complaints and information to meet the MDR requirements as part of their internal quality control system.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
Importer Reporting, Death and Serious Injury—803.40 and 803.42.	112	25	2,800	0.35 (21 minutes).	980

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

The number of respondents for each CFR section in table 3 was identified from the MDRs reported to FDA's internal databases during the period recently.

Since the publication of the 60 day notice we have adjusted our burden estimate. Our estimated burden for the information collection reflects an increase of 155,360 total burden hours and a corresponding increase of 1,566,458 total annual responses. This increase corresponds with data obtained from our database.

Dated: July 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16034 Filed 7–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0706]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2022

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2022 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2018 (ADUFA IV), authorizes FDA to collect user fees for certain animal drug applications and supplemental animal drug applications, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2022.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *Lisa.Kable@fda.hhs.gov.* For general questions, you may also email FDA's Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12) establishes four different types of user fees: (1) Fees for certain types of animal drug applications and supplemental animal drug applications; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j–12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FYs 2019 through 2023, the FD&C Act establishes aggregate yearly base revenue amounts for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts are subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)(2) and (3)). Beginning with FY 2021, the annual fee revenue amounts are also subject to adjustment to reduce workload-based increases by the amount of certain excess collections or to account for certain collection shortfalls (21 U.S.C. 379j–12(c)(3) and (g)(5)). Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: (1) Revenue from application fees shall be 20 percent of total fee revenue; (2) revenue from product fees shall be 27 percent of total fee revenue; (3) revenue from establishment fees shall be 26 percent of