TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section and activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
§ 1107.1(b) Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request Including § 25.40 Preparation of an Environmental Assessment					
§ 1107.1(b)—Preparation of tobacco product exemption from substantial equivalence request and § 25.40—Preparation of an environmental assessment	682	1	682	24	16,368
Total Hours (§ 1107.1(b))					16,368
§ 1107.1(c) Preparation of Additional Information for Tobacco Product Exemption From Substantial Equivalence Request					
§ 1107.1(c)—Preparation of additional information for tobacco product exemption from substantial equivalence request	150	1	150	3	450
Total Hours (§ 1107.1(c))					450
Section 905(j)(1)(A)(ii) of the FD&C Act: If exemption granted, report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)					
Abbreviated report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)	186	1	186	2	372
Total Hours (section 905(j)(1)(A)(ii)) of the FD&C Act					372
Total Hours Exemptions From Substantial Equivalence Requirements					17,190

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

FDA estimates that we will receive 682 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 16,368 hours. We have reduced the number of respondents from 812 to 682 based on the average number of applications received during the past 3 years.

FDA further estimates that we will receive 150 submissions requiring additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information for a total of 450 hours.

FDA estimates that 186 respondents will prepare an Abbreviated Report, as required by section 905(j)(1)(A)(ii) of the FD&C Act, with each report taking approximately 2 hours to prepare for a total of 372 hours. We have reduced the number of respondents as required by section 905(j)(1)(A)(ii) (Abbreviated Reports) from 1,217 to 186 based on the average authorizations issued during the past 3 years.

Our estimated burden for the information collection reflects an overall decrease of 5,182 hours and 1,161 total respondents. We attribute this adjustment to the number of submissions we received over the past 3 years. Therefore, FDA now estimates the burden for exemptions from substantial equivalence requirements is 17,190 hours.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18183 Filed 9–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1873]

William Goldsmith: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring William Goldsmith 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. Goldsmith was convicted of one felony count under Federal law for introducing misbranded drugs into interstate commerce. The factual basis supporting Mr. Goldsmith's conviction, as described below, is conduct relating to the importation of a drug into the United States. Mr. Goldsmith 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 August 19, 2025 (more than 30 days after receipt of the notice), Mr. Goldsmith had not responded. Mr. Goldsmith'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 September 19, 2025.

ADDRESSES: Any application by Mr. Goldsmith for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time 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–2024–N–1873. 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. 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. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On March 18, 2024, Mr. Goldsmith was convicted in the United States District Court for the Southern District of Illinois when the court accepted his plea of guilty and entered judgment against him for the offense of introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. 331(a) and 333(a)(2) (sections 301(a) and 303(a)(2) of the FD&C Act). The underlying facts supporting the conviction are as follows: As contained in the Stipulation of Fact, Mr. Goldsmith was the registered agent of Malosi Fitness Corporation (Malosi) in Illinois. Through Malosi's website Mr. Goldsmith sold and dispensed products labeled as ''Ma'Kava,'' ''Ma'Kava Private Stock,'' and ''Night Cap X,'' all of which were marketed as ''all natural'' male sexual performance enhancement supplements to hundreds of purchasers located throughout the United States. The labels of the products Mr. Goldsmith sold claimed the products included only ''natural'' herbal ingredients. In reality, the products Mr. Goldsmith sold contained sildenafil citrate, which was not listed as an ingredient on the labels of any of the products he sold. Sildenafil citrate is the active pharmaceutical ingredient in Viagra, a prescription drug approved by FDA for the treatment of erectile dysfunction. The Ma'Kava products Mr. Goldsmith sold were drugs within the meaning of section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)) because they were intended to be used to treat erectile dysfunction.

Mr. Goldsmith ordered and received raw sildenafil from companies in China and India in one-kilogram packages. Mr. Goldsmith mixed the raw sildenafil he received with other ingredients and placed the mixture into empty capsules. Mr. Goldsmith packaged these capsules into small bottles, printed with labels he made but which did not list sildenafil citrate as an ingredient on the labels. Mr. Goldsmith shipped his products containing the imported sildenafil citrate to customers across the United States. The selling of sildenafil generated Mr. Goldsmith more than $250,000 in gross proceeds.

FDA sent Mr. Goldsmith, by certified mail, on May 29, 2024, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Goldsmith was convicted, within the meaning of section 306(l)(1) of the FD&C Act, of a felony under federal law. This conviction for introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. 331(a) and 333(a)(2) (sections 301(a) and 303(a)(2) of the FD&C Act) was for conduct relating to the importation of any drug or controlled substance into the United States, as discussed above. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Goldsmith's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Goldsmith of the proposed debarment and offered him 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 him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Goldsmith received the proposal and notice of opportunity for a hearing on

June 7, 2024. Mr. Goldsmith failed to request a hearing 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 Division of Field Enforcement, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. William Goldsmith has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Goldsmith is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). 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 any drug by, with the assistance of, or at the direction of Mr. Goldsmith is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18213 Filed 9–18–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0706]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Environmental Impact Considerations

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 October 20, 2025.

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 0910–0322. 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.

Environmental Impact Considerations

OMB Control Number 0910–0322—Extension

FDA is requesting OMB approval for the reporting requirements contained in the FDA collection of information ''Environmental Impact Considerations.'' The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 106(b) of NEPA provides for the preparation of an environmental impact statement (EIS) for a proposed Federal Agency action requiring an environmental document that has a reasonably foreseeable significant effect on the quality of the human environment. Section 106(b) of NEPA further provides for the preparation of an environmental assessment (EA) for a proposed Federal Agency action that does not have a reasonably foreseeable significant effect on the quality of the human environment, or if the significance of such effect is unknown, unless the Agency finds that the proposed Federal Agency action is excluded pursuant to one of the Federal Agency's categorical exclusions (CE). Certain classes of actions that a Federal Agency has determined normally do not, individually or cumulatively, have a significant effect on the quality of the human environment are ordinarily—or categorically—excluded from the requirement to prepare an EA or EIS (see, *e.g.,* section 106(a) of NEPA).

This information collection supports implementation of NEPA, consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service (PHS) Act. Certain requests for FDA action require the preparation of a CE, EA, or EIS. FDA's regulations in part 25 (21 CFR part 25) implement the portions of NEPA that are relevant to FDA in a manner that is consistent with FDA's authority under the FD&C Act and the PHS Act. These regulations (Environmental Impact Considerations) set forth FDA procedures with regard to NEPA requirements by identifying actions that require the preparation of an environmental document and discussing the preparation of such documents. These regulations also supplement the procedures included in the ''HHS General Administration Manual, part 30: Environmental Protection'' (45 FR 76519, November 19, 1980).

A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Section 25.15(a) and (d) specifies the procedures for submitting to FDA a claim for a categorical exclusion. Extraordinary circumstances (§ 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded that may result in the need for an EA. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specify the content requirements for EAs for non-excluded actions. Where the Agency finds that no significant environmental effects is expected, a finding of no significant impact is prepared.

This collection of information is used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse events cannot be avoided, the submitted information is used to prepare and circulate to the public an EIS, when applicable, made