I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act.'' Section 505(o)(4) of the FD&C Act (21 U.S.C. 355(o)(4)) authorizes FDA to require application holders for certain drugs [1] to make labeling changes based on new safety information, including information related to reduced effectiveness, that becomes available after approval of the drug that FDA determines should be included in the labeling of the drug.

In the **Federal Register** of July 30, 2013 (78 FR 45930), FDA announced the availability of a guidance for industry entitled ''Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act'' (available at *https://www.fda.gov/media/116594/download*) (the 2013 guidance). The 2013 guidance provided information on the implementation of section 505(o)(4) of the FD&C Act, including a description of the types of safety labeling changes (SLCs) that generally may be required under this section; how FDA determines what constitutes new safety information; the procedures involved in requiring SLCs; and enforcement of the requirements for SLCs.

In 2018, Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271) (SUPPORT Act) which, among other things, changed the statutory definition of *adverse drug experience* in section 505–1(b)(1) of the FD&C Act. The SUPPORT Act also revised section 505(o)(4) of FD&C Act to define new information to include ''information related to reduced effectiveness.''

This draft guidance revises and, when finalized, will replace the guidance for industry of the same name issued on July 30, 2013 (78 FR 45930). Updates in this draft guidance include the addition of information related to Congress' 2018 changes to the definition of *adverse drug experience* regarding reduced effectiveness such as the clarification that the Agency can require changes to labeling to include information about a serious risk that results from reduced effectiveness. Additional changes were made reflecting current SLC processes and procedures adding a description of how FDA reviews and acts on SLCs when new safety information applies to multiple application holders, and clarifying when FDA may disclose SLC notification and order letters.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).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 ''Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD&C Act.'' 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. The 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 part 314 pertaining to the submission of new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplements to NDAs and ANDAs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to biologics license applications (BLAs) and supplements to BLAs have been approved under OMB control number 0910–0338. The collections of information pertaining to medication guides for prescription drug products have been approved under OMB control number 0910–0393. The collections of information pertaining to the labeling of human prescription drug and biological products have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18152 Filed 9–18–25; 8:45 am]

BILLING CODE 4164–01–P

[1] For the purposes of the *Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry*, references to *drug* include drug products approved under section 505 of the FD&C Act (21 U.S.C. 355) and biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), other than biological products that also meet the definition of a device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0378]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request, Exemptions From Substantial Equivalence Requirements for Tobacco Products

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 0910–0684. 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.

Exemptions From Substantial Equivalence Requirements for Tobacco Products

OMB Control Number 0910–0684 Extension

This information collection supports Food and Drug Administration regulations. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Tobacco products are governed by chapter IX of the FD&C Act (sections 900 through 920) (21 U.S.C. 387 through 387t). Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended, defines a tobacco product as ''any product made or derived from tobacco or containing nicotine from any source that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).''

The FD&C Act requires that before a new tobacco product may be introduced or delivered for introduction into interstate commerce, the new tobacco product must undergo premarket review by FDA. FDA must issue an order authorizing the commercial distribution of the new tobacco product or find the product exempt from the requirements of substantial equivalence under section 910(a)(2)(A) of the FD&C Act, before the product may be introduced into commercial distribution.

FDA has established a pathway for manufacturers to request exemptions from the substantial equivalence requirements of the FD&C Act in § 1107.1 (21 CFR 1107.1) of the Agency's regulations. As described in § 1107.1(a), FDA may exempt tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, from the requirement of demonstrating substantial equivalence if the Agency determines that: (1) the modification would be a minor modification of a tobacco product that can be sold under the FD&C Act, (2) a report demonstrating substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, and (3) an exemption is otherwise appropriate.

Section 1107.1(b) states that a request for exemption under section 905(j)(3) of the FD&C Act may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product and that the manufacturer must submit the request and all information supporting it to FDA. The request must be made in an electronic format that FDA can process, review, and archive (or a written request must be made by the manufacturer explaining in detail why the manufacturer cannot submit the request in an electronic format and requesting an alternative means of submission to the electronic format).

An exemption request must contain: (1) The manufacturer's address and contact information; (2) identification of the tobacco product(s); (3) a detailed explanation of the purpose for the modification; (4) a detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of the existing tobacco additive; (5) a detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the FD&C Act; (6) a detailed explanation of why a report under section 905(j)(1) of the FD&C Act intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; (7) a certification (*i.e.,* a signed statement by a responsible official of the company) summarizing the supporting evidence and providing the rationale for the official's determination that the modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictiveness, or abuse liability; (8) other information justifying an exemption; and (9) an environmental assessment (EA) under part 25 (21 CFR part 25) prepared in accordance with the requirements of § 25.40.

The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4347) states national environmental objectives and imposes on each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement for every major Federal action that will significantly affect the quality of the human environment.

The FDA NEPA regulations are contained in part 25. All applications for exemption from substantial equivalence require the submission of 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) specifies the content requirements for EAs for nonexcluded actions.

The information required by § 1107.1(b) is submitted to FDA so FDA can determine whether an exemption from substantial equivalence to the product is appropriate for the protection of the public health. Section 1107.1(c) states that FDA will review the information submitted and determine whether to grant or deny an exemption based on whether the criteria in section 905(j)(3) of the FD&C Act are met. FDA may request additional information, if necessary, to make a determination and may consider the exemption request withdrawn if the information is not provided within the requested timeframe.

This collection of information also contains a requirement that a manufacturer submit a report (referred to as an ''abbreviated report'') at least 90 days prior to making an introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product. Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, a report must be submitted to FDA that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all of the modifications are covered by exemptions granted by the Secretary of Health and Human Services (the Secretary) under section 905(j)(3).

In the **Federal Register** of June 27, 2025 (90 FR 27623), 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 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