more indications for which the biosimilar or interchangeable biosimilar product is licensed.

- To receive licensure for an additional indication.
- To remove an approved indication.
- To receive an initial determination of interchangeability.

Supplements to approved applications under section 351(k) of the PHS Act that do not meet the criteria under Categories A through F are outside the scope of this guidance.

This guidance is intended to help applicants identify the appropriate classification category and review goal date of the supplement being submitted. Section I.A. of the commitment letter associated with the BsUFA III sets forth these supplement classification categories and their associated review performance goals. The full text of the proposed BsUFA III Commitment Letter can be found on the Agency's web page ''BsUFA III: Fiscal Years 2023–2027,'' available at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027*.

This guidance finalizes the draft guidance entitled ''Classification Categories for Certain Supplements Under BsUFA III'' issued on August 11, 2023 (88 FR 54626). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarification that the guidance does not include recommendations for manufacturing-only supplements or for all supplements for safety-related updates to the labeling, clarification that applicants can request reconsideration of classification category with appropriate justification, and clarification that a pediatric assessment or amended initial pediatric study plan may be included in a Category D supplement. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Classification Categories for Certain Supplements Under BsUFA III.'' 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 OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information pertaining to the Biosimilar User Fee Program and for the submission of biologics license applications under section 351(k) of the PHS Act regarding biosimilar product applications, interchangeable biosimilar product applications, and supplemental applications have been approved under OMB control number 0910–0718. The collections of information in 21 CFR 201.56 and 201.57 for the submission of labeling have been approved under OMB control number 0910–0572. The collections of information pertaining to Medication Guides for prescription human drug and biological products have been approved under OMB control number 0910–0393. The collections of information in 21 CFR part 601 for the submission of biologics license applications, supplemental applications, and Form FDA 356h have been approved under OMB control number 0910–0338.

III. Electronic Access

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–17290 Filed 9–8–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5943]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Product Establishment Registration and Listing

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 9, 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 0910–0650. 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.

Tobacco Product Establishment Registration and Listing

OMB Control Number 0910–0650—Revision

This information collection supports the Food and Drug Administration (FDA, us, or we) regulations and guidance. Tobacco products are generally governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 921) (21 U.S.C. 387 through 21 U.S.C. 387u).

Section 905 of the FD&C Act requires the annual registration of any ''establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.'' Section 905 of the FD&C Act requires this registration be completed by December 31 of each year. The Secretary of Health and Human Services (Secretary) has delegated to the FDA Commissioner the responsibility for administering the FD&C Act, including section 905. Section 905 of the FD&C Act requires owners or operators of each establishment to register: (1) their name; (2) places of business; (3) a list of all tobacco products which are manufactured by that person; (4) a copy of all labeling and a reference to the authority for the marketing of any tobacco product subject to a tobacco

product standard under section 907 of the FD&C Act (21 U.S.C. 387g) or to premarket review under section 910 of the FD&C Act (21 U.S.C. 387j); (5) a copy of all consumer information and other labeling; (6) a representative sampling of advertisements; (7) upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and (8) upon request made by the Secretary, if the registrant has determined that a tobacco product contained in the product list is not subject to a tobacco product standard established under section 907 of the FD&C Act, a brief statement of the basis upon which the registrant made such determination.

FDA collects the information submitted pursuant to section 905 of the FD&C Act through the Tobacco Registration and Product Listing Module Next Generation (TRLM NG) electronic portal, and through paper forms; Form FDA 3741, ''Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments,'' available at *www.fda.gov/media/77915/download,* and Form FDA 3741a, ''Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishments,'' available at *www.fda.gov/media/99863/download,* for those individuals who are unable to submit online through TRLM NG. TRLM NG is designed to streamline the data entry process for registration and product listing. FDA strongly encourages electronic submission through TRLM NG, available at *www.fda.gov/tobacco-products/manufacturing/tobacco-registration-and-listing-module-next-generation-trlm-ng-instructions,* to facilitate efficiency and timeliness of data submission and management.

FDA has published a guidance for industry titled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments'' (March 2023; *www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM191940.pdf*). This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA.

At this time, FDA is proposing several updates to the information submitted pursuant to section 905 of the FD&C Act through Form FDA 3741, Form FDA 3741a, and the corresponding information submitted electronically through TRLM NG. The updates include: (1) merging the contents of Form FDA 3741a into Form FDA 3741 to create an updated and comprehensive Form FDA 3741, ''Registration and Product Listing of Tobacco Product Manufacturing Establishments''; (2) restructuring and developing sections of the updated Form FDA 3741 for ease of navigation and data input; (3) updating terminology of the updated Form FDA 3741 for clarity; (4) updating instructions of the updated Form FDA 3741 for clarity; and (5) aligning tobacco product categories and subcategories of the updated Form FDA 3741 to be consistent with other FDA tobacco forms. Since the publication of the 60-day **Federal Register** notice, the following changes have been applied to the updated Form FDA 3741: (1) material file data elements have been added and are captured in TRLM NG; and (2) product listing updates can be entered directly in TRLM NG and relevant data elements have been added to Form FDA 3741 in case of paper submissions. Finally, as discussed in the 60-day **Federal Register** notice, FDA is proposing to add Form FDA 3741b, a new product listing spreadsheet, to this information collection. FDA anticipates the new Form FDA 3741b will streamline product listing submissions and subsequent FDA review. Since the publication of the 60-day **Federal Register** notice, the following changes have been applied to the product listing spreadsheet (Form FDA 3741b): (1) removal of the ''Material Files'' tab, which will now be captured through TRLM NG user interface as part of Form FDA 3741; (2) restriction of form usage to initial product list submissions only, as this form will be used exclusively for initial submissions; (3) addition of ''Universal Product Code'' field to improve data quality and traceability; (4) removal of multiple data elements regarding manufacturer information, product marketing, and product status fields from the spreadsheet, which will be incorporated into Form FDA 3741 and TRLM NG for improved efficiency.

Although these proposed updates will increase the overall length of the updated and comprehensive Form FDA 3741 and the corresponding information submitted electronically through TRLM NG, FDA anticipates these updates will streamline the navigation and completion of Form FDA 3741, reduce redundancies, increase overall user efficiency and ultimately enable industry to more accurately convey the required registration and listing information to FDA as required by section 905 of the FD&C Act. Both current versions of Form FDA 3741, ''Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments''; and Form FDA 3741a, ''Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishments'', will be discontinued upon implementation of the updated and comprehensive Form FDA 3741, ''Registration and Product Listing of Tobacco Product Manufacturing Establishments''.

Section 904(a)(1) of the FD&C Act requires that each tobacco product manufacturer or importer submit ''a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand'' by December 22, 2009. This section applies only to those tobacco products manufactured and distributed before June 22, 2009, and which are still manufactured as of the date of the ingredient listing submission.

Section 904(c) of the FD&C Act requires that a tobacco product manufacturer: (1) provide all information required under section 904(a) of the FD&C Act to FDA ''at least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment''; (2) advise FDA in writing at least 90 days prior to adding any new tobacco additive or increasing in quantity an existing tobacco additive, except for those additives that have been designated by FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use; and (3) advise FDA in writing at least 60 days of such action of eliminating or decreasing an existing additive, or adding or increasing an additive that has been designated by FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use.

FDA collects the information submitted pursuant to section 904(a)(1) and 904(c) of the FD&C Act through an electronic portal, and through a paper form (Form FDA 3742, ''Listing of Ingredients in Tobacco Products'' available at *www.fda.gov/media/77661/download*) for those individuals who choose not to use the electronic portal.

In addition to the development of the electronic portal and paper form, FDA published a guidance titled ''Listing of Ingredients in Tobacco Products'' (March 2023; *www.fda.gov/regulatory-information/search-fda-guidance-documents/listing-ingredients-tobacco-products*). This guidance is intended to assist persons making tobacco product

ingredient listing submissions. FDA also provides a technical guide, embedded hints, and a web tutorial to the electronic portal, available at *www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions.* The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product [1] [2] to be subject to Chapter 9 of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah tobacco, pipe tobacco, nicotine gels, and dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976) (''the final deeming rule'').

In the **Federal Register** of January 17, 2025 (90 FR 5909), 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]

FDA form/activity/FD&C act section	Number of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
Establishment Registration (Initial), the initial registration of a tobacco product establishment using Form FDA 3741, Form FDA 3741a, and the new Form FDA 3741 (Electronic and Paper submissions) [2] Sections 905(b), 905(c), 905(d), 905(h), or 905(i).	37	1	37	1.65 (99 minutes)	61
Establishment Registration (Renewal), the registration renewal of a tobacco product establishment using Form FDA 3741, Form FDA 3741a, and the new Form FDA 3741 (Electronic and Paper submissions) [3] Sections 905(b), 905(c), 905(d), 905(h), or 905(i).	900	1	900	0.28 (17 minutes)	252
Product Listing (Initial), the initial listing of tobacco products (New) Form FDA 3741b, ''Tobacco Product List Spreadsheet''.	37	1	37	0.22 (13 minutes)	8
Tobacco Product Listing Form FDA 3742, ''Listing of Ingredients in Tobacco Products'' Section 904(a)(1).	16	1	16	2 (120 minutes)	32
Tobacco Product Listing Form FDA 3742, ''Listing of Ingredients'' Section 904(c).	37	10	370	0.40 (24 minutes)	148
Obtaining a Dun & Bradstreet D–U–N–S Number	37	1	37	0.5 (30 minutes)	19
Total			1,397		520

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This initial submission is averaged over the three years of the information collection utilizing the current Form FDA 3741 and 3741a, which will be combined in updated Form FDA 3741 in Spring 2026.
[3] This renewal submission is averaged over the three years of the information collection utilizing the current Form FDA 3741 and 3741a, which will be combined in Form FDA 3741 ''Registration and Product Listing of Tobacco Product Manufacturing Establishments'' with product listing and material file information updates.

Since publication of the 60-day **Federal Register** notice, we have revised our estimates to consolidate like activities, and the estimated annual reporting burden for establishment registration and product listing based on updated center data. We believe this is a more accurate picture of what our annualized burden would be. FDA has based these estimates on experience with this information collection, information we have available from interactions with industry, registration and listing reports, and TRLM NG.

FDA estimates that the updated Form FDA 3741 will be available and required to be used by tobacco product manufacturers in Spring 2026. As mentioned previously in this notice, this new form will replace both the current Form FDA 3741 and Form 3741a, which is scheduled to be discontinued in Spring 2026. To capture this consolidation accurately in the burden table, we have combined like activities from the 60-day **Federal Register** notice and averaged the burden

[1] Tobacco Product: as stated in section 201(rr) of the FD&C Act in relevant part, a tobacco product: (1) means 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); and (2) does not mean an article that is a drug defined under section 201(g)(1) of the FD&C Act, a device defined under section 201(h) of the FD&C Act, or a combination product described in section 503(g) of the FD&C Act, or a food under section 201(f) of the FD&C Act if it contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

[2] Premium Cigars: on August 9, 2023, the U.S. District Court for the District of Columbia issued an order vacating FDA's rule deeming tobacco products to be subject to FDA's tobacco product authorities ''insofar as it applies to premium cigars.'' *Cigar Ass'n of Am.* v. *FDA,* No. 16–cv–01460, Dkt. No. 277 (D.D.C. Aug. 9, 2023), appeal filed No. 23–5220 (D.C. Cir. Sep. 29, 2023).

For purposes of its ruling, the court specified that premium cigars are those cigars that:

(1) are wrapped in whole tobacco leaf; (2) contain a 100 percent leaf tobacco binder; (3) contain at least 50 percent (of the filler by weight) long filler tobacco; (4) are handmade or hand rolled; (5) have no filter, nontobacco tip, or nontobacco mouthpiece; (6) do not have a characterizing flavor other than tobacco; (7) contain only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weigh more than 6 pounds per 1,000 units.

FDA recognizes that, absent further relief, it is bound by the District Court's order. The Agency is continuing to evaluate the evolving legal and practical circumstances surrounding premium cigars and will provide further information as it is available.

over the 3-year approved information collection request (ICR) period for a more comprehensive burden table.

Based on updated data, we have revised our estimate for sections 905(b), 905(c), 905(d), 905(h), or 905(i) of the FD&C Act. Based on FDA's experience with current establishment registration and product listing information submitted to the agency, FDA has lowered the estimated annual respondents for (1) initial tobacco product establishment registration and listing (via Form FDA 3741) from 200 to 37 respondents, and (2) renewal of tobacco product establishment and listing (via Form FDA 3741) from 2,572 to 900 respondents.

The agency estimates that up to 37 new establishments will each submit one initial establishment registration and product listing via the current Form FDA 3741. The agency retains the hours per response estimate of 1.60 hours (or 96 minutes) for the initial tobacco product establishment registration and listing via the current Form FDA 3741, which FDA estimates manufacturers will need to use through the first year of the 3-year ICR approval period. Once the updated Form FDA 3741 is released, FDA estimates its completion to take 1.67 hours (100 minutes) for an initial registration of a tobacco product establishment and material file submission. As shown in Table 1, averaged across the 3-year ICR period, FDA estimates an average annual burden of 1.65 hours (99 minutes) for a total of 61 burden hours (across the 37 annual respondents). FDA estimates up to 37 establishments will each submit 1 initial product listing spreadsheet each year using the new Form FDA 3741b, which is expected to take 0.33 hours (20 minutes), for a total of 12 burden hours. Averaged across the 3-year ICR approval period, FDA estimates an average annual hours per response of 0.22 hours (8 average total hours) because, as noted above, the agency estimates that tobacco product manufacturers will not start using this new form until Year 2 of the 3-year ICR approval period.

Based on updated data, FDA estimates that the annual number of respondents for establishment registration and product listing renewals required under FD&C Act section 905 (Form FDA 3741) will decrease from 2,572 to 900. FDA retains the hours per response estimate of 10 minutes (0.17 hours) for the registration renewal via the current Form FDA 3741, which FDA estimates manufacturers will need to use through the first year of the 3-year ICR approval period. For Years 2 and 3, FDA estimates that the updated Form FDA 3741 will take 20 minutes (0.33 hours) for registration renewal. The renewal time increases with the updated Form FDA 3741 because the consolidated registration renewal process now encompasses establishment registration, product listing updates, and material file updates. Averaged across the 3-year ICR period, FDA estimates an average annual burden of 0.28 hours (17 minutes) for a total of 252 burden hours (across the 900 annual respondents).

FDA estimates that the submission of ingredient listings required by section 904(a)(1) of the FD&C Act for each establishment will take 2 hours initially. Ingredients may be submitted electronically through the CTP Portal Next Generation or if unable to submit ingredients electronically then by mail using Form FDA 3742. FDA estimates that 16 establishments will initially submit one report annually at 2 hours per report, for a total of 32 hours.

Based on FDA's experience and the number of new products authorized to be introduced or delivered for introduction into interstate commerce submitted over the past 3 years, FDA estimates that 37 establishments will each submit 10 reports (one every 6 months). FDA also estimates that the confirmation or updating of product (ingredient) listing information required by section 904(c) of the FD&C Act is expected to take 0.40 hour (24 minutes) for a total 148 burden hours. FDA estimates that obtaining a D–U–N–S number will take 30 minutes. FDA assumes that all new establishment facilities that will be required to initially register under section 905 of the FD&C Act would obtain a D–U–N–S number. FDA estimates that up to 37 establishments that would need to obtain this number each year. The total industry burden to obtain a D–U–N–S number is 19 hours.

Our estimated burden for the information collection reflects an overall decrease of 442 hours and a decrease of 1,861 annual responses. We attribute this adjustment to the proposed revisions to this information collection to add the updated and comprehensive Form FDA 3741, ''Registration and Product Listing of Tobacco Product Manufacturing Establishments'' and add Form FDA 3741b, ''Tobacco Product List Spreadsheet''.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–17222 Filed 9–8–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2102]

Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations; 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 final guidance for industry entitled ''Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations.'' This guidance describes the Agency's recommendations on the design and evaluation of comparative analytical studies intended to support a demonstration that a proposed therapeutic protein product is biosimilar to a reference product licensed under the Public Health Service Act (PHS Act). Additionally, this guidance is intended to provide recommendations to sponsors on the scientific and technical information for the chemistry, manufacturing, and controls (CMC) portion of a marketing application for a proposed product submitted under the PHS Act. This guidance finalizes and replaces the draft guidance of the same title issued on May 22, 2019, and replaces the final guidance ''Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product'' issued on April 30, 2015.

DATES: The announcement of the guidance is published in the **Federal Register** on September 9, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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