exemptions for investigational use of food additives, the granting of requests for exemption from regulation as a food additive under 21 CFR 170.39 of this chapter, and allowing notifications submitted under 21 U.S.C. 348(h) to become effective, unless categorically excluded in § 25.32(b), (c), (i), (j), (k), (l), (o), (q), or (r).

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for CEs listed under § 25.32(i) and (q) that the Agency has received in the past 3 years. To avoid counting the burden attributed to § 25.32(o) as zero, we have estimated the burden for this claim of CE at one respondent making one submission a year for a total of one annual submission. The burden for submitting a claim of CE is captured under § 25.15(a) and (d).

Based on a review of the information collection since our last request for OMB approval, we have made adjustments to our burden estimate. Our estimated burden for the information collection reflects an overall increase of 215,125 hours and a decrease of 1,938 responses.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18188 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–2012–D–0429]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Meetings With Industry and Investigators on the Research and Development of 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 0910–0731. 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.

Meetings With Industry and Investigators on the Research and Development of Tobacco Products

OMB Control Number 0910–0731—Extension

This information collection supports FDA guidance. 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 21 U.S.C. 387t). The FD&C Act offers tobacco product manufacturers several pathways to obtain an order from FDA to authorize the marketing of a new tobacco product before it may be introduced or delivered into interstate commerce.

To provide assistance with these pathways to market products, FDA will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) when appropriate as described in FDA's guidance titled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised)'' (September 2022; *www.fda.gov/regulatory-information/search-fda-guidance-documents/meetings-industry-and-investigators-research-and-development-tobacco-products-revised*). This guidance is intended to assist persons who seek meetings with FDA relating to their research to inform the regulation of tobacco products, or to support the development or marketing of tobacco products.

This guidance describes two collections of information: (1) the submission of a meeting request containing certain information and (2) the submission of an information package in advance of the meeting. The purpose of this proposed information collection is to allow FDA to conduct meetings with tobacco manufacturers, importers, researchers, and investigators in an effective and efficient manner. FDA issued this guidance and the revisions consistent with FDA's good guidance practices regulations (21 CFR 10.115).

Meeting Requests: The guidance sets forth FDA's recommendations for materials to be included in a request for a meeting with FDA to discuss the research and development of tobacco products. In the guidance, FDA recommends that the following information be included in the meeting request:

1. Product name;
2. FDA-assigned Submission Tracking Number(s) of prior submissions (*e.g.,* premarket applications, meeting requests) for the product and relevant product version(s) (if applicable);
3. Product category (*e.g.,* cigarettes, smokeless tobacco) (if applicable);
4. Product use (indicate for consumer use or for further manufacturing);
5. Contact information for the authorized point of contact for the company requesting the meeting;
6. The topic of the meeting being requested (*e.g.,* a new tobacco product application, an application for permission to market a modified risk tobacco product, or proposed investigational use of a new tobacco product);
7. A brief statement of the purpose of the meeting, which could include a discussion of the types of studies or data to be discussed at the meeting, the general nature of the primary questions to be asked, and where the meeting fits in the overall product development plans;
8. A preliminary list of the specific objectives/outcomes expected from the meeting;
9. A preliminary proposed agenda, including an estimate of the time needed and a designated speaker for each agenda item;
10. A preliminary list of specific critical questions, grouped by discipline (*e.g.,* chemistry, clinical, nonclinical);
11. A list of all individuals who will attend the meeting on behalf of the

tobacco product manufacturer, importer, researcher, or investigator, including titles, responsibilities, and if applicable, identification of prior FDA employment;

12. The date on which the meeting information package will be received by FDA; and

13. Suggested format of the meeting (*e.g.,* conference call, in-person meeting at FDA offices, video conference, or written response) and suggested dates and times for the meeting.

Meetings are usually scheduled for 1 hour. FDA is proposing the inclusion of a new recommendation that a meeting request identify prior FDA employment for any individual who will attend the meeting on behalf of the tobacco product manufacturer, importer, researcher, or investigator, if applicable. This information would indicate if the individual is subject to certain post-government employment restrictions.

This information contained in the meeting request will be used by the agency to: (1) determine the utility of the meeting, (2) identify agency staff necessary to discuss proposed agenda items, and (3) schedule the meeting.

Meeting Information Packages: An individual submitting a meeting information package to FDA in advance of a meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the individual or FDA to be discussed at the meeting. As stated in the guidance, FDA recommends that meeting information packages generally include updates of information that was submitted with the meeting request and, as applicable:

1. Product composition and design data summary;

2. Manufacturing and process control data summary;

3. Nonclinical data summary;

4. Clinical data summary;

5. Behavioral and product use data summary;

6. User and nonuser perception data summary; and

7. Investigational plans for studies and surveillance of the tobacco product, including a summary of proposed study protocols containing the following information (as applicable):

a. Study objective(s);

b. Study hypotheses;

c. Study design;

d. Study population (inclusion/exclusion criteria, comparison group(s));

e. Human subject protection information, including Institutional Review Board information;

f. Primary and secondary endpoints (definition and success criteria);

g. Sample size calculation;

h. Data collection procedures;

i. Duration of follow up and baseline and follow up assessments, and

j. Data analysis plan(s).

The purpose of the meeting information package is to provide agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. In the agency's experience, reviewing such information is critical to achieving a productive meeting. If the meeting information package was previously submitted in the meeting request, it should be revised, as applicable, so that the information reflects the most current and accurate information available. As discussed in the guidance document, electronic submission is not required, although we strongly encourage electronic submission via the CTP Portal Next Generation (CTP Portal NextGen) using FDA's eSubmitter tool. Instructions on obtaining a CTP Portal NextGen account are available at *www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal-next-generation.*

In the **Federal Register** of June 27, 2025 (90 FR 27636), 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]

Activity; guidance section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests					
Combining and sending meeting request letters for manufacturers, importers, and researchers; Guidance section III.E	20	1	20	12	240
Meeting Information Packages					
Combining and submitting meeting information packages for manufacturers, importers, and researchers; Guidance section III.K	20	1	20	18	360
Total					600

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

Following the publication of the 60-day **Federal Register** notice, FDA has revised the annual number of respondents from 60 to 20 for this information collection. The original figure of 60 represented the total number of respondents across a three-year period rather than an annual average.

FDA's estimate of the number of respondents for meeting requests in Table 1 is based on the number of meeting requests received and projected over the next three years. FDA estimates that 60 meetings will be requested over the next three years (20 each year on average). Between the previous information collection and this extension, we have revised this estimate from 65 respondents to 20 respondents annually. The hours per response for combining and sending meeting request letters are estimated at 12 hours each, and the total burden hours for meeting requests are expected to be 240 hours. We have revised the average burden per response from 10 hours to 12 hours. Based on FDA's experience, the agency expects it will take respondents 240 hours to prepare, gather, copy, and submit brief statements about the product and a description of the purpose and details of the meeting, including identifying prior FDA employment for any individual who will attend the meeting on behalf of the

tobacco product manufacturer, importer, researcher, or investigator.

FDA estimates that 20 respondents will compile and submit meeting information packages at 18 hours per response. Based on FDA's experience, the agency expects that it will take respondents, collectively, 360 hours to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information that generally would already have been generated for the planned research and/or product development.

The total annual number of burden hours for this collection of information is estimated to be 600 hours (240 hours to prepare and submit meeting requests and 360 hours to prepare and submit information packages). Our estimated burden for the information collection reflects an overall decrease of 1,220 hours and a corresponding decrease of 45 responses.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18184 Filed 9–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DEPARTMENT OF AGRICULTURE

[Docket No. FDA–2025–N–1793]

Ultra-Processed Foods; Request for Information; Extension of Comment Period

AGENCY: Food and Drug Administration (FDA), U.S. Department of Health and Human Services (HHS); U.S. Department of Agriculture (USDA).

ACTION: Notice; request for information; extension of comment period.

SUMMARY: FDA and USDA (we) are extending the comment period for the notice that appeared in the **Federal Register** of July 25, 2025. In the notice, we requested data and information to help develop a uniform definition of ultra-processed foods (UPF or UPFs). In response to requests for an extension, we are extending the comment period until October 23, 2025, to allow interested persons additional time to submit comments.

DATES: We are extending the comment period announced in the notice published July 25, 2025 (90 FR 35305). Electronic or written comments must be submitted by October 23, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 23, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2025–N–1793 for ''Ultra-Processed Foods; Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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.'' We will review this copy, including the claimed confidential information, in our consideration of comments. 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 comments 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 to read background documents or the electronic and written/paper comments received, 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

FDA: Claudine Kavanaugh, Office of Nutrition and Food Labeling, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301–796–4647; or Meadow Platt, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

USDA: Eve Stoody, Food and Nutrition Service, United States Department of Agriculture, 1320 Braddock Place, Alexandria, VA 22314, 703–305–2062.