burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by May 19, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–P–0015A Medicare Current Beneficiary Survey

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey; *Use:* CMS is the largest single payer of health care in the United States. The agency plays a direct or indirect role in administering health insurance coverage for more than 120 million people across the Medicare, Medicaid, CHIP, and Exchange populations. A critical aim for CMS is to be an effective steward, major force, and trustworthy partner in supporting innovative approaches to improving quality, accessibility, and affordability in healthcare. CMS also aims to put patients first in the delivery of their health care needs.

The Medicare Current Beneficiary Survey (MCBS) is the most comprehensive and complete survey available on the Medicare population and is essential in capturing data not otherwise collected through our operations. The MCBS is a nationally-representative, longitudinal survey of Medicare beneficiaries that we sponsor and is directed by the Office of Enterprise Data and Analytics (OEDA). MCBS data collection includes both in-person and phone interviewing. The survey captures beneficiary information whether aged or disabled, living in the community or facility, or serviced by managed care or fee-for-service. Data produced as part of the MCBS are enhanced with our administrative data (*e.g.,* fee-for-service claims, prescription drug event data, enrollment, etc.) to provide users with more accurate and complete estimates of total health care costs and utilization. The MCBS has been continuously fielded for more than 30 years, encompassing over 1.2 million interviews and more than 140,000 survey participants. Respondents participate in up to 11 interviews over a four-year period. This gives a comprehensive picture of health care costs and utilization over a period of time.

The MCBS continues to provide unique insight into the Medicare program and helps CMS and our external stakeholders better understand and evaluate the impact of existing programs and significant new policy initiatives. In the past, MCBS data have been used to assess potential changes to the Medicare program. For example, the MCBS was instrumental in supporting the development and implementation of the Medicare prescription drug benefit by providing a means to evaluate prescription drug costs and out-of-pocket burden for these drugs to Medicare beneficiaries. Beginning in 2024, this proposed revision to the clearance will add a few new measures to existing questionnaire sections and will remove COVID–19-related content that is no longer relevant for administration. Updated respondent materials are also included in this request. The revisions will result in a net decrease in respondent burden as compared to the current clearance due to the removal of COVID–19 items. *Form Number:* CMS–P–0015A (OMB control number: 0938–0568); *Frequency:* Occasionally; *Affected Public Sector:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 13,568; *Total Annual Responses:* 35,015; *Total Annual Hours:* 34,380. (For policy questions regarding this collection contact Bill Long at 410–786–7927).

Dated: March 15, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–05628 Filed 3–17–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–3261]

Definition of the Term ''Tobacco Product'' in Guidances Issued Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing conforming changes to its guidances issued under the Federal Food, Drug, and Cosmetic Act (FD&C

Act) as required by the Consolidated Appropriations Act of 2022, which amended the term ''tobacco product'' in the FD&C Act to include products that contain nicotine from any source.

DATES: Conforming changes to reflect the changes to FDA's guidance are made beginning March 20, 2023.

ADDRESSES: You may submit comments on any guidance 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 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 name of the guidance(s) that the comments address and the docket number for the guidance(s) (see table 1). Received comments will be placed in the docket(s) 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.'' The Agency will review this copy, including the claimed confidential information, in its 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 (see table 1) 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Paul Hart or Laura Chilaka, Center for Tobacco Products (CTP), Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended by the Tobacco Control Act, defined the term ''tobacco product'' to mean any product made or derived from tobacco 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). It further stated that the term ''tobacco product'' does not mean an article that is a drug under section 201(g)(1), a device under section 201(h), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)).

The Consolidated Appropriations Act of 2022 (the Appropriations Act) (Pub. L. 117–103), enacted on March 15, 2022, amended the definition of the term ''tobacco product'' in section 201(rr) of the FD&C Act to include products that contain nicotine from any source. It further amended the definition to exclude articles that are foods under section 201(f) of the FD&C Act if such articles contain no nicotine or no more than trace amounts of naturally occurring nicotine. The Appropriations Act also amended section 901(b) of the FD&C Act (21 U.S.C. 387a(b)), which concerns FDA authority over tobacco products, by adding a sentence stating chapter IX of the FD&C Act shall also apply to any tobacco product containing nicotine that is not made or derived from tobacco. As a result, tobacco products that contain non-tobacco nicotine (NTN), including synthetic nicotine, are now subject to the provisions in chapter IX of the FD&C Act (21 U.S.C. 387 to 387t), including but not limited, to the:

- Adulteration and misbranding provisions (sections 902 and 903 of the FD&C Act);
- Required submission of ingredient listing and reporting of harmful and potentially harmful constituents for all tobacco products (section 904 of the FD&C Act);

- Required establishment registration and product listing (section 905 of the FD&C Act);
- Prohibition of selling tobacco products to individuals under 21 years of age (section 906(d)(5) of the FD&C Act);
- Requirement that new tobacco products have an FDA marketing order (section 910 of the FD&C Act) in effect; and
- Requirement that modified risk tobacco products have a modified risk order in effect (section 911 of the FD&C Act).

The Appropriations Act further states that products that are tobacco products under the amended definition in section 201(rr) of the FD&C Act shall be subject to all requirements of regulations for tobacco products and specifies that the term ''tobacco product'' in regulations and guidance issued, in whole or in part, under the FD&C Act shall have the meaning of, and shall be deemed amended to reflect the meaning of, the amended definition in section 201(rr). As a result, beginning April 14, 2022, tobacco products that contain NTN, including synthetic nicotine, are subject to the provisions that apply to tobacco products in FDA's regulations, including, but not limited to:

- Refuse to accept criteria for premarket submissions (21 CFR 1105.10);
- Content and format requirements for premarket tobacco product applications (21 CFR part 1114);
- Exemption from substantial equivalence requirements (21 CFR part 1107, subpart A); and
- Prohibition of the distribution of free samples (21 CFR 1140.16(d)).

The Appropriations Act directs FDA to publish a notice in the **Federal Register** to update the Code of Federal Regulations (CFR) to reflect the deemed amendment to existing regulations and guidance. Accordingly, in this notice we are making conforming changes to reflect the statutory amendments made by the Appropriations Act to tobacco product guidance issued in whole or in part under the FD&C Act. Elsewhere in this edition of the **Federal Register**, we are issuing a final amendment to make conforming changes to regulations to reflect the statutory amendments made by the Appropriations Act.

II. Description of Changes to FDA Guidances

FDA is updating the definition of ''tobacco product'' in guidances issued, in whole or in part, under the FD&C Act, to reflect the amendments made by the Appropriations Act. The definition of ''tobacco product,'' where included in the text of FDA guidance, is being updated to reflect the statutory amendments by adding the phrase ''or containing nicotine from any source'' after the words ''from tobacco,'' and incorporating the exclusion of articles that are foods as defined in section 201(f) of the FD&C Act if such articles contain no nicotine or no more than trace amounts of naturally occurring nicotine.

The guidance documents listed in table 1 are, or will be,[1] updated to reflect the statutory amendments made by the Appropriations Act. In certain cases, FDA is also making Level 2 changes to these guidance documents for clarity in light of the statutory amendments.

TABLE 1—UPDATED GUIDANCE DOCUMENTS

Title of guidance	Docket No.	OMB control No. (if applicable) [1]
FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements*.	FDA–2014–N–0189	N/A.
Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems.	FDA–2015–D–2496	Refers to previously approved FDA collections of information.
Interpretation of and Compliance Policy for Certain Label Requirements; Applicability for Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops.	FDA–2017–D–0120	N/A.
Listing of Ingredients in Tobacco Products*	FDA–2009–D–0524	0910–0650.
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments*.	FDA–2009–D–0508	0910–0650.
Health Document Submission Requirements for Tobacco Products*	FDA–2009–D–0600	0910–0654.
Prohibition of Distributing Free Samples of Tobacco Products	FDA–2017–D–0113	N/A.
Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers	FDA–2010–D–0431	N/A.
Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.	FDA–2011–D–0147	0910–0673.
Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order.	FDA–2015–D–0404	N/A.
Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007*.	FDA–2011–D–0125	0910–0775.
Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products.	FDA–2011–N–0121	N/A.

[1] See section III of this document for additional information about the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) as it relates to these guidance documents.

These revised final guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115) and represent the current thinking of FDA on the topic discussed in each guidance. They do not establish any legally enforceable rights or responsibilities for any person and are not legally binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. You may submit comments on any guidance at any time (see **ADDRESSES**).

III. Paperwork Reduction Act of 1995

The amendments made by the Appropriations Act result in changes to

[1] Guidance titles in table 1 marked with an asterisk will be published in updated form as changes are finalized or when the associated information collections are updated in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

some previously approved collections of information that are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The OMB control numbers for these information collections are listed in table 1. FDA has published, and intends to continue publishing, notices concerning proposed changes to the relevant information collection activities in other editions of the **Federal Register**. In addition, in compliance with the PRA, we will submit revisions to the current information collections to OMB for review.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance documents at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: February 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03951 Filed 3–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–1941]

Determination of Regulatory Review Period for Purposes of Patent Extension; JIVI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for JIVI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by May 19, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 18, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 May 19, 2023. 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–2019–E–1941 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; JIVI.'' 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.'' The Agency will review this copy, including the claimed confidential information, in its 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 section 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: