proposed action. Interested persons are invited to send comments regarding our 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 March 23, 2026.

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**).

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 Collections

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Participation Report; *Use:* The collected baseline data is used to assess the effectiveness of state early and periodic screening, diagnostic and treatment (EPSDT) programs in reaching eligible children (by age group and basis of Medicaid eligibility) who are provided initial and periodic child health screening services, referred for corrective treatment, and receiving dental, hearing, and vision services. This assessment is coupled with the state's results in attaining the participation goals set for the state. The information gathered from this report, permits federal and state managers to evaluate the effectiveness of the EPSDT law on the basic aspects of the program. *Form Number:* CMS–416 (OMB control number 0938–0354); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,128. (For policy questions regarding this collection contact Deirdra Stockmann at 410–786–2433.)

2. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Initial Request for State Implemented Moratorium Form; *Use:* Congress has enacted section 1866 (j)(7) of the Social Security Act, which allows for the imposition of temporary moratorium. CMS promulgated 42 CFR 424.570 in order to comply with that statute, which requires that prior to implementing state Medicaid moratoria the state Medicaid agency must notify the Secretary in writing, including all of the details of the moratoria, and obtain the Secretary's concurrence with the imposition of the moratoria.

The Initial Request for State Medicaid Implemented Moratorium, named the ''Initial Request for State Medicaid Implemented Moratorium'' has been created to collect that data, in a uniform manner, which the states report to CMS when they request a moratorium. Currently, CMS is collecting this data on an ad-hoc basis, however this process needs to be standardized so that moratoria decisions are being made based on the same criteria each time. The form may be used by states and territories who wish to impose a Medicaid or Children's Health Insurance Program moratorium. CMS will use this information as a standardized method to collect and track state-imposed moratoria requests. *Form number:* CMS–10628 (OMB control number: 0938–1328); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 5; *Number of Responses:* 5; *Total Burden Hours:* 25. (For questions regarding this collection contact Alisha Sanders at 410–786–0671).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–01196 Filed 1–21–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–2243]

FDA Records Access Authority for Cosmetics; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft document entitled ''FDA Records Access Authority for Cosmetics: Guidance for Industry.'' The draft guidance document provides answers to frequently asked questions about certain authorities for FDA to access records related to cosmetic products. It is intended to inform regulated industry about the Agency's current thinking regarding the criteria, process, and expectations for FDA's access to these records.

DATES: Submit either electronic or written comments on the draft guidance by March 23, 2026 to ensure that the Agency considers your comment on this

draft guidance before it begins work on the final version of the guidance.

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 Docket No. FDA–2025–D–2243 for ''FDA Records Access Authority for Cosmetics: Guidance for Industry.'' Received comments 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 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.

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

Submit written requests for single copies of the draft guidance to the Division of Inspectorate Policy, Office of Inspections and Investigations, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send one self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Nadine Dominique, Office of Inspections and Investigations, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20857, 301–348–1868, *Nadine.Dominique@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''FDA Records Access Authority for Cosmetics: Guidance for Industry.'' 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 this topic. 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.

On December 29, 2022, the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), which included the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), was signed into law. Among other provisions, MoCRA added sections 605 (21 U.S.C. 364a) and 610 (21 U.S.C. 364f) to, and amended section 704(a)(1) (21 U.S.C. 374(a)(1)) of, the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing new authorities for FDA to access and copy records related to cosmetic products for inspection. Section 605 specifies that the Secretary has access to adverse event records during an inspection under section 704 (21 U.S.C. 374). Section 610 authorizes FDA to access and copy certain records if FDA has a reasonable belief that a cosmetic product, including an ingredient in the product, and any other cosmetic product that FDA reasonably believes is likely to be affected in a similar manner, is likely to be adulterated such that the use or exposure to such product presents a threat of serious adverse health consequences or death to humans (SAHCODH). Section 704(a)(1) of the FD&C Act, as amended by section 3504 of MoCRA, extends FDA's inspectional authority over all records and other information described in sections 605 and 610 from facilities that manufacture and process cosmetic products, when the standard for those sections apply. This draft guidance focuses on the authorities to access records described in sections 605 (adverse event reports), 610 (SAHCODH), and 704 (inspections).

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. 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 sections 605 and 610 of the FD&C Act have been approved under 0910–0599.

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* or *https://www.regulations.gov*.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–01159 Filed 1–21–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–3942]

Labeling and Preventing Cross-Contact of Gluten for Packaged Foods; Request for Information

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

ACTION: Petition for rulemaking; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) received a citizen petition from Celiac Journey requesting that we act to protect consumers with celiac disease by requiring that all ingredients with gluten be listed by name in the ingredient list and by requiring cross-contact controls with gluten-containing grains. We are issuing this document to request comment on the issues raised in the petition and on specific questions related to these issues.

DATES: Submit either electronic or written comments and scientific data and information by March 23, 2026.

ADDRESSES: You may submit comments and information 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 March 23, 2026. 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–2023–P–3942 for ''Labeling and Preventing Cross-Contact of Gluten for Packaged Foods; Request for Information.'' Received comments 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: Carol D'Lima, Office of Nutrition and Food Labeling (HFS–800), Nutrition Center of Excellence, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; Meridith L. Kelsch, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

A. Citizen Petition

In September 2023, Celiac Journey submitted a citizen petition (Docket No. FDA–2023–P–3942) requesting that FDA act to protect consumers with celiac disease (CD) by better enabling them to identify, through labeling, whether a food includes gluten-containing grains (GCGs), and to address cross-contact with GCGs. For purposes of this document, GCGs refers to the cultivated crops that have naturally occurring gluten protein. These include wheat (*Triticum*), rye (*Secale*), barley (*Hordeum*), and crossbreeds like triticale (crossbreed of rye and wheat). Celiac Journey's petition, in part, asks that FDA: (1) issue a rule to require that all ingredients with gluten be listed by name in the ingredient lists of all foods, and (2) add gluten to the list of allergens