

discussion. Topics can be related to specific data-sharing matters or specific biomarkers of interest where discussion of translation would facilitate coordinated research efforts.

3. Please provide input on specific biomarkers that are commonly collected but not yet accepted as an endpoint and have the potential to significantly support regulatory decisions related to safety or efficacy, for which aggregation of data across multiple programs may advance drug development.

IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at <https://www.regulations.gov> as these references are copyright protected. Some may be available at the website address, if listed. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Chen J, J Florian, W Carter, RD Fleischer, TS Hammerstrom, PR Jadhav, W Zeng, J Murray, and D Birnkrant, 2013, Earlier Sustained Virologic Response End Points for Regulatory Approval and Dose Selection of Hepatitis C Therapies, *Gastroenterology*, 144(7):1450–1455.e2, epub ahead of print March 5, 2013, doi: 10.1053/j.gastro.2013.02.039.

Kalaria SN, TR Farchione, R Uppoor, M Mehta, Y Wang, and H Zhu, 2021, Extrapolation of Efficacy and Dose Selection in Pediatrics: A Case Example of Atypical Antipsychotics in Adolescents With Schizophrenia and Bipolar I Disorder, *Journal of Clinical Pharmacology*, 61: S117–S124, doi: 10.1002/jcph.1836.

Kalaria SN, TR Farchione, MV Mathis, M Gopalakrishnan, I Younis, R Uppoor, M Mehta, Y Wang, and H Zhu, 2020, Assessment of Similarity in Antipsychotic Exposure-Response Relationships in Clinical Trials Between Adults and Adolescents With Acute Exacerbation of Schizophrenia, *Journal of Clinical Pharmacology*, 60(7): 848–859, doi: 10.1002/jcph.1580.

(Authority: 21 CFR part 10 and 21 U.S.C. 357.)

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–09533 Filed 5–12–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–4126]

Azodicarbonamide (ADA); Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting information on the current uses and safety data of azodicarbonamide (ADA) in human food and as a food contact substance. We are requesting this information as part of our systematic process for conducting post-market assessments of chemicals in food. We are conducting a post-market assessment of the safety of ADA in food, considering the latest state of the science. We intend to use the information received and any other available, relevant information to determine if ADA remains safe under its current conditions of use in food and as a food contact substance.

DATES: Either electronic or written comments and scientific data and information on the notice must be submitted by July 13, 2026.

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 July 13, 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–2026–N–4126 for “Azodicarbonamide (ADA); 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: Daniel Hlavaty, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301-796-1481, or Lauren Kleinman, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting information on the current uses and safety data for azodicarbonamide (ADA) in human food and as a food contact substance as part of a post-market assessment. ADA (CAS No. 123-77-3) is used as a whitening agent in cereal flour and as a dough conditioner in breadmaking and has applications in manufacturing food contact materials.

All uses of ADA in food or as a food contact substance must be authorized for that use through a food additive regulation or an effective food contact notification, or be excluded from regulation as a food additive, for example, because such use is generally recognized as safe (GRAS) or is prior sanctioned (see Sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act). As described below, these uses of ADA in food and as a food contact substance in the U.S. are authorized by FDA's food additive regulations.

ADA is authorized as a direct food additive when used as an aging and bleaching ingredient in cereal flour and as a dough conditioner in bread baking in a total amount not to exceed 0.0045 percent (45 parts per million; 2.05 grams per 100 pounds of flour) (21 CFR 172.806). It is listed as an optional ingredient in the standards of identity for bread, rolls, and buns (21 CFR 136.110); flour (21 CFR 137.105); and whole wheat flour (21 CFR 137.200)

when used in accordance with the regulations for ADA in 21 CFR 172.806. ADA is also permitted as an indirect food additive when used in closures with sealing gaskets for food containers (21 CFR 177.1210), rubber articles intended for repeated use (21 CFR 177.2600), and adjuvant substances used in the manufacture of foamed plastics (21 CFR 178.3010). We are not aware of any prior sanctions or conclusions that the use of ADA is GRAS in food or for food contact use.

As part of our systematic review of chemicals in food, FDA is beginning a post-market assessment of the safety of ADA as used in food and as a food contact substance. (see <https://www.fda.gov/food/food-chemical-safety/list-select-chemicals-food-supply-under-fda-review>). This assessment supports the Make America Healthy Again Commission's recommendation to implement an evidence-based systematic process for post-market assessment of chemicals in food (see <https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf>). The objective of our assessment is to determine if ADA is safe under its conditions of use in food or as a food contact substance considering the most recent science. While FDA previously concluded authorized uses to be safe, new information may require reconsideration of the regulatory status or the safe uses of a substance in or on food.

II. Request for Information

FDA is requesting information on uses, use levels, dietary exposure, and safety data on ADA currently used in food and as a food contact substance. This includes decomposition products of ADA, which are the chemicals formed when ADA breaks down, such as during breadmaking. Information from food manufacturers on uses and levels is crucial for food chemical assessments. We encourage food manufacturers to participate in this data call, with options for aggregated submissions through trade groups or other collaborations. We do not need information about individual products and their recipes, but rather data about the levels of use in general product categories. Voluntary submission of data and information on current uses and use levels will help to refine our dietary exposure assessments. We use maximizing assumptions to estimate dietary exposure (see, e.g., "Guidance for Industry: Estimating Dietary Intake of Substances in Food," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry->

estimating-dietary-intake-substances-food). Without refinements assisted by manufacturer use information, this may lead to overestimation of dietary exposure that could impact authorizations for the chemical's use in food or as a food contact substance.

Specifically, FDA requests the following:

1. General food categories in which ADA is used (for example, cookies, soft drinks, other categories listed in 21 CFR 170.3(n)), USDA's What We Eat in America survey (Ref. 1), or the Codex General Standard for Food Additives (Ref. 2));
2. Typical and maximum use levels of ADA in each applicable general food category;
3. Information on actual or expected residual levels of decomposition products of ADA (including semicarbazide and ethyl carbamate) in foods and food contact materials where ADA is used;
4. Information on the current food contact uses of ADA, including data on migration of ADA or its decomposition products from food contact materials into food;
5. Subpopulations with high dietary exposure to ADA or its decomposition products or particular safety concerns relevant to food and food contact uses of ADA;
6. Other dietary sources of ADA or its decomposition products, such as dietary supplements, natural occurrence in common foods, residues in animal products, or as contaminants in food or drinking water;
7. Market share of foods in each applicable general food category and food contact materials that are formulated with ADA;
8. Biomonitoring data for ADA, its decomposition products, or its metabolites;
9. Updated market disappearance or poundage data for ADA;
10. Information on potential chemically or pharmacologically related substances used in food or as a food contact substance;
11. Safety data relevant to use of ADA in food or as a food contact substance, including data pertaining to its decomposition products, and especially unpublished data;
12. Documentation of GRAS conclusions or prior sanctions for uses of ADA in food or as a food contact substance;
13. Information that may support the conclusion that ADA is no longer used for one or more of its authorized intended uses in food or as a food contact substance.

III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. What We Eat in America Food Categories, available at <https://www.ars.usda.gov/>

*northeast-area/beltsville-md-bhnrc/
beltsville-human-nutrition-research-
center/food-surveys-research-group/
docs/dmr-food-categories/.*

2. Codex General Standard for Food Additives, available at <https://www.fao.org/gsfaonline/foods/index.html>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-09508 Filed 5-12-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-1600]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; The Real Cost Campaign Outcomes Evaluation Study: Cohort 3

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 June 12, 2026.

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 0910-0915. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@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.

The Real Cost Campaign Outcomes Evaluation Study: Cohort 3

OMB Control Number 0910-0915—Revision

This information collection supports the development and implementation of FDA public education campaigns related to tobacco use. FDA’s Center for Tobacco Products (CTP) was created to carry out the authorities granted under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) to educate the public about the dangers of tobacco use and to serve as a public health resource for tobacco and health information. CTP’s tobacco education mission directly contributes to advancing the goals of Executive Order 14212: Establishing the President’s Make America Healthy Again Commission, including the Make Our Children Health Again assessment, in three ways. First, CTP works to reduce tobacco use, the leading cause of chronic disease and mortality in the United States. Second, CTP protects the health of children; public education campaigns and other CTP efforts decrease the likelihood that youth initiate or escalate tobacco use. Third, CTP uses gold-standard science to develop, implement, and evaluate its programs.

FDA launched “The Real Cost” educational campaigns in February 2014, seeking to reduce tobacco use among at-risk youth in the United States who are open to using or have already experimented with cigarettes or electronic nicotine delivery systems (ENDS). As with CTP as a whole, FDA’s “The Real Cost” Youth Cigarette and E-Cigarette Prevention Campaigns aim to reduce chronic disease and protect the health of children. “The Real Cost” campaigns use evidence-based messaging distributed through multiple channels, including paid media advertising, to highlight the negative health consequences of tobacco use to U.S. youth. The Real Cost Campaign Outcomes Evaluation Study, also known as the Evaluation of FDA’s Public Education Campaign on Teen Tobacco (ExPECTT) study, uses gold-standard science to measure exposure, awareness, and impact of “The Real Cost” campaigns among youth in the United States.

The first ExPECTT study (Cohort 1) assessed the campaign’s impact on outcome variables of interest from November 2013 to November 2016. The second ExPECTT study (Cohort 2; OMB Control No. 0910-0753) assessed the

campaign’s impact on outcome variables of interest from June 2018 to August 2022. The third ExPECTT study (Cohort 3; OMB Control No. 0910-0915) has been assessing the campaign’s impact on outcome variables of interest starting in February 2023. To continue assessing the impact of “The Real Cost” campaigns, FDA intends to extend implementation of the ExPECTT Cohort 3 study. The study consists of multiple waves of data collection, including a baseline survey and up to eight continuing follow-up (FU) surveys, conducted approximately 6–9 months apart. The online surveys are conducted with youth ages 11–17 at baseline (for mail-based recruitment).

The purpose of FDA’s ExPECTT Cohort 3 study is to provide credible evidence that changes in key outcomes can be attributed to exposure to the campaign. Using gold-standard science, FDA can determine the strength of the attribution and rule out alternative explanations for observed changes in key outcomes. In the ExPECTT study, FDA has been measuring variation in both potential campaign exposure (e.g., market-level delivery) and self-reported campaign exposure to media advertising and how those exposures relate to key outcomes.

The goal of ExPECTT Cohort 3 is to determine whether future waves of “The Real Cost” public education campaigns will continue to influence the following key outcomes:¹

- Awareness of campaign messages
- Tobacco use behaviors (such as initiation, escalation, cessation)
- Specific beliefs targeted by messages (message-targeted beliefs)
- Psychosocial predictors or precursors of tobacco use behavior
 - Health and addiction risk perceptions
 - Perceived loss of control or threat to freedom expected from tobacco use
 - Anticipated guilt, shame, and regret from tobacco use
 - Perceptions of prevalence, approval, and popularity of tobacco use
 - Pro-health changes in normative beliefs about tobacco product use
 - Tobacco use susceptibility
 - Intention or willingness to use tobacco
 - Intention to quit and/or reduce daily consumption

In support of the provisions of the Tobacco Control Act (Pub. L. 111-31) that require FDA to protect the public health and to reduce tobacco use by

¹ MacMonegle, A., Zarndt, A.N., Wang, Y., Bennett, M., Malo, V., Pitzer, L., . . . & Duke, J. (2025). The Impact of “The Real Cost” on E-cigarette Initiation among US Youth. *American Journal of Preventive Medicine*.