



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-0490]

Policy Regarding N-acetyl-L-cysteine: Draft Guidance for Industry; Availability

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

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled “Policy Regarding N-acetyl-L-cysteine: Draft Guidance for Industry.” The draft guidance, when finalized, will explain our intent to exercise enforcement discretion with respect to the sale and distribution of certain products that contain N-acetyl-L-cysteine (NAC) and are labeled as dietary supplements. This enforcement discretion policy would apply to products that would be lawfully marketed dietary supplements if NAC were not excluded from the definition of “dietary supplement” and that are not otherwise in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.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-2022-D-0490 for “Policy Regarding N-acetyl-L-cysteine: Draft 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.” 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.

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 Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Gerie Voss, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-620-9744; or Lauren Ferguson Baham, Center for Food Safety and Applied

Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “Policy Regarding N-acetyl-L-cysteine: Draft Guidance for Industry.” We are issuing the draft guidance consistent with our 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 alternate approach if it satisfies the requirements of the applicable statutes and regulations.

FDA has determined that, under section 201(ff)(3)(B)(i) of the FD&C Act (21 U.S.C. 321(ff)(3)(B)(i)), NAC is excluded from the dietary supplement definition because NAC was approved as a new drug before it was marketed as a dietary supplement or as a food. FDA received two citizen petitions requesting that we conclude that NAC is not excluded from the definition of dietary supplement under section 201(ff)(3)(B) of the FD&C Act. On March 31, 2022, we denied this request.

In addition, one of the citizen petitions asked FDA “to recommend and support to the Secretary of HHS” that he issue a regulation that would determine NAC to be lawful under the FD&C Act. As we stated in our response to the citizen petitions, we have not yet reached a final decision on this request, but we are considering initiating rulemaking under section 201(ff)(3)(B) of the FD&C Act to permit the use of NAC in or as a dietary supplement (i.e., to provide by regulation that NAC is not excluded from the definition of dietary supplement), and, if, among other considerations, FDA does not identify safety-related concerns as we continue our review of the available data and information, we are likely to propose a rule providing that NAC is not excluded from the definition of dietary supplement. While our full safety review of NAC remains ongoing, our initial review has not revealed safety concerns with respect to the use of

this ingredient in or as a dietary supplement. In addition, NAC-containing products represented as dietary supplements have been sold in the United States for more than 30 years, and consumers continue to seek access to such products.

Accordingly, the draft guidance, if finalized, would state our intent to exercise enforcement discretion with respect to the sale and distribution of certain products that contain NAC and are labeled as dietary supplements. The enforcement discretion policy would apply to products that would be lawfully marketed dietary supplements if NAC were not excluded from the definition of “dietary supplement” and that are not otherwise in violation of the FD&C Act. Unless we identify safety-related concerns during our ongoing review, FDA would intend to exercise enforcement discretion until either of the following occurs: we complete notice-and-comment rulemaking to allow the use of NAC in or as a dietary supplement (if we move forward with such proceedings), or we deny the citizen petition’s request for rulemaking. Should we determine that this enforcement discretion policy is no longer appropriate, we will notify stakeholders by withdrawing or revising this guidance in accordance with 21 CFR 10.115.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information.. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/FoodGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

