Dated: July 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0490]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Policy Regarding N-acetyl-L-cysteine.'' The guidance explains 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 applies 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: The announcement of the guidance is published in the **Federal Register** on August 2, 2022.

ADDRESSES: You may submit either electronic or written comments on FDA guidances 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: 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 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 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 guidance.

FOR FURTHER INFORMATION CONTACT: Lisa Bieniek, Center for Food Safety and Applied Nutrition, Office of Dietary Supplements and Programs (HFS–810), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–4528; or Lauren 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 guidance for industry entitled ''Policy Regarding N-acetyl-L-cysteine: Guidance for Industry.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents 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.

In the **Federal Register** of April 22, 2022 (87 FR 24170), we made available a draft guidance for industry entitled ''Policy Regarding N-acetyl-L-cysteine: Draft Guidance for Industry,'' which explained 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. In the draft guidance, we explained FDA 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. We described that FDA denied 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.

In addition, we described that one citizen petition asked FDA to issue a regulation that would determine NAC to be lawful under the FD&C Act. We described that we have not yet reached a final decision on this request, but 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). If, among other considerations, we do 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.

We gave interested parties an opportunity to submit comments by May 23, 2022, to ensure their comments would be considered before we began work on the final version of the guidance. We received comments on the draft guidance that misinterpreted the guidance as converting NAC into a ''drug'' under the FD&C Act. Our guidance does not convert NAC into a ''drug'' under the FD&C Act. Rather, our guidance states 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. We also received comments that supported 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, as well as comments that supported possible notice-and-comment rulemaking to allow the use of NAC in or as a dietary supplement. After careful review and consideration of the comments to the draft guidance, we are finalizing the guidance without substantive change.

As discussed in the guidance, the enforcement discretion policy applies 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 intends 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 withdraw or revise this guidance in accordance with 21 CFR 10.115.

The guidance announced in this notice finalizes the draft guidance, dated April 2022.

II. Paperwork Reduction Act of 1995

FDA concludes that this 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 guidance at either *https://www.fda.gov/FoodGuidances, https://www.fda.gov/CosmeticGuidances, 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: July 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16499 Filed 8–1–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0478]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 1, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–0478 30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Unified Hospital Data Surveillance System (U.S. Healthcare COVID–19 Collection).

Type of Collection: Emergency Revision.

OMB No.: 0990–0478.

Abstract: Since March 29, 2020, the U.S. government has been collecting data from hospitals and states to understand health care system stress, capacity, capabilities, and the number of patients hospitalized due to COVID–19. The principal use of the data collected through this ICR is to inform federal allocations of limited supplies (*e.g.,* protective equipment and medication). It is also used to inform the White House, conduct research on hospitalization, and communicate to the public through daily and weekly reports for the public's use and analysis.

Hospitals, with the exception of psychiatric and rehabilitation hospitals, are required to report seven days a week but, where possible and pending further direction from their state or jurisdiction, are encouraged to report weekend data on the following Monday with the data backdated to the appropriate date. Data elements may be required or optional and may be associated with a specific cadence. Some data elements are requested at each reporting interval (*i.e.,* daily), while others are requested weekly. As of the August 10, 2022 guidance, per Secretary discretion, psychiatric and rehabilitation facilities must submit data once annually for the