DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: To receive Head Start funding, Head Start grant recipients must apply for such funds through this information collection. The information submitted by applicants assists program and grant officials in determining whether the applicant meets the requirements for funding under the Head Start Act including any requirements specified in annual appropriations by Congress.

Respondents: Head Start grant recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Head Start Grant Application	1,600	2.5	25	100,000

Estimated Total Annual Burden Hours: 100,000.

Authority: 42 U.S.C. 9801 *et seq.*

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–08651 Filed 4–21–22; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0759]

Drug Products, Including Biological Products, That Contain Nanomaterials; 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 Agency) is announcing the availability of a final guidance for industry entitled ''Drug Products, Including Biological Products, That Contain Nanomaterials.'' This guidance finalizes the draft guidance issued December 18, 2017, developed to provide industry with the Agency's current thinking for the development of human drug products, including those that are biological products, in which a nanomaterial is present in the finished dosage form. The guidance also includes recommendations for applicants and sponsors of investigational, premarket, and postmarket submissions for these products.

DATES: The announcement of the guidance is published in the **Federal Register** on April 22, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency 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–2017–D–0759 for ''Drug Products, Including Biological Products, That Contain Nanomaterials.'' 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Kavita Vyas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4154, Silver Spring, MD, 20993–0002, 301–796–4787; or Stephen Ripley, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD, 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Drug Products, Including Biological Products, That Contain Nanomaterials.'' This guidance applies to human drug products, including those that are biological products, in which a nanomaterial is present in the finished dosage form. This guidance discusses both general principles and specific considerations for developing drug products containing nanomaterials through abbreviated pathways. Considerations for quality, nonclinical, and clinical studies are discussed as they relate to drug products containing nanomaterials throughout product development and production.

This guidance finalizes the draft guidance issued December 18, 2017 (82 FR 60019). There were two noteworthy changes made from the draft version to final guidance in response to stakeholder comments. First, the final guidance provides a glossary of terminology to assist in understanding how important terms are used in the document. Second, several revisions were made to reflect FDA's current thinking with respect to abbreviated applications, including abbreviated new drug applications (ANDAs), for products containing nanomaterials. In addition to changes in response to comments, the final guidance document's discussion regarding over-the-counter (OTC) monograph drugs has been updated for consistency with the enactment of OTC reform provisions of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Drug Products, Including Biological Products, That Contain Nanomaterials.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information, related to investigational new drug applications, in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information, related to new drug applications and ANDAs, including supplemental applications, in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), regarding biosimilar applications, have been approved under OMB control number 0910–0718. The collections of information, related to biologics license applications, in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information, related current good manufacturing process requirements, in 21 CFR part 211 have been approved under OMB control number 0910–0139. The collections of information, related to environmental impact requirements, in 21 CFR part 25 have been approved under OMB control number 0910–0322. The collections of information related to controlled correspondence regarding generic drug development have been approved under OMB control number 0910–0797.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08572 Filed 4–21–22; 8:45 am]

BILLING CODE 4164–01–P

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