collections of information in 21 CFR part 314 regarding the submission of new drug applications including formal meetings with sponsors and applicants for Prescription Drug User Fee Act products, abbreviated new drug applications and supplemental applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to the submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information relating to expedited program for serious conditions for drug and biological product development programs have been approved under OMB control number 0910–0765. The collections of information pertaining to the submission of special protocol assessments have been approved under OMB control number 0910–0470. The collections of information in 21 CFR 201.56 and 201.57 for the submission of certain prescription drug product labeling have been approved under OMB control number 0910–0572. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0130. The collections of information pertaining to good clinical practice have been approved under OMB control number 0910–0843. The collections of information pertaining to adverse events reporting have been approved under OMB control number 0910–0291.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09170 Filed 4–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0451]

Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the draft guidance entitled ''Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Guidance for Industry,'' which was announced in the **Federal Register** of February 23, 2023. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the draft guidance published February 23, 2023 (88 FR 11449). Submit either electronic or written comments on the draft guidance by July 31, 2023, 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–2023–D–0451 for ''Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request.'' 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: Jeanmaire Hryshko, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; or Philip Chao, 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: In the **Federal Registe**r of February 23, 2023 (88 FR 11449), we published a notice of availability for a draft guidance entitled ''Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request.'' This action opened a docket with a 60-day comment period.

We have received requests for a 90-day extension of the comment period for the draft guidance. We have concluded that it is reasonable to reopen the comment period for 90 days, until July 31, 2023. We are reopening the comment period because the request for an extension of the comment period arrived too late for us to extend the comment period. We believe that an additional 90 days allows adequate time for interested persons to submit comments.

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09176 Filed 4–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0875]

S12 Nonclinical Biodistribution Considerations for Gene Therapy Products; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, 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 ''S12 Nonclinical Biodistribution Considerations for Gene Therapy Products.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The final guidance provides harmonized recommendations for the conduct and overall design of nonclinical biodistribution (BD) studies for gene therapy (GT) products. The recommendations in the guidance endeavor to facilitate the development of investigational GT products, while avoiding unnecessary use of animals, in accordance with the 3Rs (reduce/refine/replace) principles. The final guidance replaces the draft guidance entitled ''S12 Nonclinical Biodistribution Considerations for Gene Therapy Products'' issued on September 9, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on May 1, 2023.

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–2021–D–0875 for ''S12 Nonclinical Biodistribution Considerations for Gene Therapy Products.'' 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