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Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09183 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–2019–D–0297]

Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products; 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 ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products; Guidance for Industry.'' The document provides guidance to assist sponsors in the clinical development of nicotine replacement therapy (NRT) drug products, including but not limited to those intended for smoking cessation and related chronic indications. This guidance finalizes the draft guidance of the same title issued on February 22, 2019.

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–2019–D–0297 for ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug 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 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: Heather Dorsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20903–0002, 240–429–4192, *heather.dorsey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products.'' This guidance reflects the FDA's current thinking regarding overall development programs to support the approval of NRT drug products for smoking cessation and related chronic indications. There are several FDA-approved prescription and nonprescription NRT drug products for cessation of smoking cigarettes, but the Agency encourages the development of additional NRT drug products, which could help more smokers quit.

The guidance focuses on drug development and trial design issues that are specific to the study of NRT drug products. NRT drug products are typically studied and labeled for use as adjuncts to behavioral self-help materials and to date have involved single treatment regimens that begin on the patient's quit day (first day without a cigarette). Alternate treatment regimens (*e.g.,* pretreatment before quit day, quitting by gradual reduction (reduce to quit), using multiple NRT drug products together) are discussed in the guidance.

As outlined in the guidance, NRT drug products can be developed for smoking cessation and/or reduction in risk of relapse. NRT drug products that first have demonstrated efficacy for at least one of these indications can also include additional information in labeling by demonstrating efficacy in certain secondary endpoints. Sponsors can evaluate reduction in the urge to smoke or relief of cue-induced craving in former smokers as secondary endpoints. Additionally, sponsors that can demonstrate, via a secondary endpoint, that the drug product provides relief of withdrawal symptoms in smokers *who are not trying to quit smoking* may be able to include labeling instructions to address situations when such individuals are required to abstain and therefore experience withdrawal symptoms (*e.g.,* while traveling on an airplane).

FDA is aware of the serious risks associated with smoking and is committed to facilitating the development of therapies to support smoking cessation efforts. Both the regulatory pathway for an NRT drug product and the amount of nonclinical or clinical data needed to support approval will depend on the characteristics of the proposed NRT drug product relative to an approved NRT drug product. This guidance outlines general considerations for NRT drug development and trial design, and FDA encourages sponsors to contact FDA for feedback on their proposed development plans. Sponsors developing nonprescription drug product should bear in mind that it is often not possible to answer all regulatory questions in a single trial, and additional sequential steps may be needed.

This guidance finalizes the draft guidance entitled ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products'' issued on February 22, 2019 (84 FR 5693). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarification that the document does not address the development of NRT to aid in the cessation of non-combustible tobacco products (*e.g.,* e-cigarettes); information regarding the pathway described in section 505(b)(2) (21 U.S.C. 355(b)(2)) of the Federal Food, Drug, and Cosmetic Act and reliance on published literature; and clarification regarding mode of administration and route of administration. In addition, editorial changes were made to improve clarity. 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 ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products.'' 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 in 21 CFR part 312 pertaining to the submissions of investigational new drug applications, including clinical trial design and study protocols, have been approved under OMB control number 0910–0014. The

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]

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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