For devices that: (1) Must bear UDIs on their labels and (2) are intended to be used more than once and reprocessed between uses, 21 CFR 801.45 requires the devices to be directly marked with a UDI. Compliance dates for these labeling, GUDID data submission, standard date format, and direct marking requirements can be found in the preamble to the UDI Rule (78 FR 58786 at 58815 to 58816). For more information about UDI compliance dates, please see the UDI web page, available at: *https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/compliance-dates-udi-requirements.*

For labelers of class I devices, FDA has developed this draft guidance to revise section III. ''Policy On Standard Date Formatting, UDI Labeling, and GUDID Submission Requirements for Class I and Unclassified Devices'' of the guidance entitled ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking'' (''2020 UDI Compliance Policy Guidance'', available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices-and*), which was issued on July 1, 2020. When this draft guidance is finalized, the updates in section III of this draft guidance would supersede the recommendations in section III of the 2020 UDI Compliance Policy Guidance. FDA considered comments received on the guidance that appeared in the **Federal Register** on July 1, 2020 (85 FR 39477) as the Agency revised the guidance.

This draft guidance explains that there are certain class I devices for which FDA does not intend to enforce GUDID submission requirements under § 830.300 and describes how a labeler of a class I device can determine if its device is considered a consumer health product. FDA has determined that the entry of UDI data into GUDID for these devices is burdensome to stakeholders. After undertaking a public health impact analysis, the Center for Devices and Radiological Health has a better understanding of the devices and device characteristics for which GUDID information is particularly useful in evaluating and improving device safety throughout a product life cycle, as well as the ones for which GUDID information may be less important in this regard. The policy proposed in this draft guidance is based on this analysis. We are proposing this change in policy through guidance to allow FDA and stakeholders an opportunity to fully assess its impact on public health. FDA will take the assessment into account in determining whether regulations on this subject should be amended in the future.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff''. 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 new 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 the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
801 subpart B and 830	Unique Device Identification	0910–0720
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17029 and complete title to identify the guidance you are requesting.

Dated: October 7, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–22308 Filed 10–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0055]

Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (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 ''Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in

Commercially Processed, Packaged, and Prepared Foods.'' The guidance describes our views on voluntary short-term (2.5-year) goals for sodium reduction in a variety of identified categories of foods that are commercially processed, packaged, or prepared. These goals are intended to address the excessive intake of sodium in the current population and promote improvements in public health.

DATES: The announcement of the guidance is published in the **Federal Register** on October 14, 2021.

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–2014–D–0055 for ''Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods.'' 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 guidance to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS–255), 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: Kasey Heintz, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1376; or Deirdre Jurand, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy, 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 ''Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods.'' 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 June 2, 2016 (81 FR 35363), we made available a draft guidance for industry entitled ''Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods.'' The draft guidance described our tentative views on voluntary short-term and long-term goals for sodium reduction in a variety of identified categories of foods that are commercially processed, packaged, or prepared. Section IV of the **Federal Register** notice, ''Issues for Consideration,'' listed eight specific questions (or ''issues'') (81 FR 35363 at 35366). The comment period for issues related primarily to short-term goals (Issues 1 through 4) was scheduled to close on August 31, 2016, and the comment period for issues related primarily to long-term goals (Issues 5 through 8) was scheduled to close on October 31, 2016. In the **Federal Register** of August 30, 2017 (81 FR 59640), we published a notice extending the comment period for Issues 1 through 4 until October 17, 2016, and for Issues 5 through 8 until December 2, 2016.

We received approximately 200 comments on the draft guidance. The comments generally recognized and

supported the benefit of sodium reduction efforts for public health. Many comments discussed the categories proposed in the draft guidance, including requests for greater clarity on our approach to establishing categories and suggestions for how certain categories should be changed. The comments also discussed sodium reduction efforts generally, including examples of successful sodium reduction across product categories or portfolios, examples of sodium reduction technologies, and examples of successful sodium reduction initiatives in other countries and jurisdictions. Some comments emphasized the barriers to sodium reduction, such as the time and cost associated with product reformulation, the standards of identity limitations for certain foods, and consumer preferences for certain kinds of ingredients. Several comments also requested more time to achieve the targets. Other general comments discussed the role of sodium in foods, recommended that we establish a monitoring plan, and recommended that we establish a comprehensive, national consumer education campaign for sodium reduction.

After careful review of the comments, we have modified the guidance to clarify the voluntary sodium targets, timeframe, product categories, and descriptions. The guidance is intended to support an average sodium intake reduction to 3,000 milligrams/day. In addition, we have extended the milestone date for the short-term goals from 2 years to 2.5 years from the publication of the final guidance. The 2.5-year goals are intended to balance the need for broad and gradual reductions in sodium and what is publicly known about technical and market constraints on sodium reduction and reformulation. We are not finalizing the long-term (10-year) sodium reduction targets discussed in the draft guidance at this time. We revised the layout as well as category names and descriptions of the sodium guidance target table to improve understanding and provide additional clarity as to how foods should be categorized, and made changes to categories where they were supported by scientific data (*e.g.,* we merged the ''Ready-to-Eat Cereal, Flakes'' category with the ''Ready-to-Eat Cereal, Puffed'' category and moved Provolone cheese from the ''Monterey Jack and Other Semi-Soft Cheese'' category to the ''Pasta Filata Cheese (soft)'' category). We also made technical corrections and editorial changes throughout the guidance to improve clarity, and included more recent data in our references.

The guidance announced in this notice finalizes the draft guidance with respect to the short-term sodium reduction goals.

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 101 have been approved under OMB control number 0910–0381. The collections of information in 21 CFR 101.11 have been approved under OMB control number 0910–0782.

III. Electronic Access

Persons with access to the internet may obtain the 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.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction or are not publications. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff or, in the case of non-publication references, at any website listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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Dated: October 8, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–22453 Filed 10–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1047]

Q13 Continuous Manufacturing of Drug Substances and Drug Products; International Council for Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled ''Q13 Continuous Manufacturing of Drug Substances and Drug Products.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance provides clarification on continuous manufacturing (CM) concepts and describes scientific approaches and regulatory considerations specific to CM of drug substances and drug products. The draft guidance is intended to provide scientific and regulatory considerations for the development, implementation, operation, and lifecycle management of CM.

DATES: Submit either electronic or written comments on the draft guidance by December 13, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins 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