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Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry; Extension of Comment Periods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment periods.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment periods for the Draft Guidance entitled, “Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods” that appeared in the Federal Register of June 2, 2016. In the notice, we requested comments on developing the sodium targets and for implementation of the guidance document. We are taking this action in response to requests to extend the two comment periods to allow interested persons additional time to submit comments.

DATES: We are extending the comment periods on the draft guidance published June 2, 2016 (81 FR 35363). Submit either electronic or written comments on Issues 1 through 4 in section IV of the notice of availability that published on June 2, 2016, by October 17, 2016. Submit either electronic or written comments on Issues 5 through 8 in section IV of the notice of availability that published on June 2, 2016, by December 2, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover.
goals, and to address FDA requirements. The requested extensions would result in a 180-day comment period for all eight Issues for Consideration. We also received comments opposed to any extensions of the comment period related to the short-term goals. These comments expressed their view that the initial comment period provided sufficient time for stakeholders to review the draft guidance and to contribute informed comments and that it is important for FDA to move forward in finalizing the short-term goals for public health reasons.

We considered the requests and are extending the comment periods for the draft guidance as follows: For Issues 1 through 4, we are extending the comment period until October 17, 2016, and for Issues 5 through 8 we are extending the comment period until December 2, 2016. We believe that these extensions allow adequate time for interested persons to submit comments without significantly delaying finalizing the guidance.


Leslie Kux,
Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Stem Cell Therapeutic Outcomes Database

AGENCY: Health Resources and Services Administration, HHS

ACTION: Notice

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 29, 2016.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (P.L.) 109–129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2015, P.L. 114–104 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. HRSA’s Healthcare Systems Bureau established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation under contract to the U.S. Department of Health and Human Services (HHS). The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who received stem cell therapeutic products and to do so using a standardized, electronic format. Data is collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes. Post-Transplant Essential Data (TED) forms are being revised in this submission. The portion of the Product Form related to confirmation of human leukocyte antigen (HLA) typing has minor changes to the identification and date fields to allow this form to more flexibly capture HLA typing data for expanding indications of cellular therapy. The Pre-TED form remains unchanged from the previously approved OMB submission.

The increase in burden is due to an increase in the annual number of transplants and increasing survivorship after transplantation.

Need and Proposed Use of the Information: HRSA uses the information to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation and provide the Secretary of HHS with an annual report of transplant center specific survival data.

Likely Respondents: Transplant Centers.