appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 21, 2016. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 13, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 14, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Lauren D. Tesh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20765 Filed 8–29–16; 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Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry; Extension of Comment Periods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

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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kasey Heintz, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1376.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 2, 2016 (81 FR 35363), we published a notice announcing the availability of a draft guidance entitled, ''Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods.'' Section IV of the notice, ''Issues for Consideration,'' listed eight specific questions (or ''issues'') and provided two comment periods for the submission of comments pertaining to these issues (81 FR 35363 at 35366). The comment period for Issues related primarily to short-term goals (Issues 1 through 4) was scheduled to end on August 31, 2016, and the comment period for issues related primarily to long-term goals (Issues 5 through 8) was scheduled to end on October 31, 2016. Comments on Issues 1 through 8 will inform our final guidance on the voluntary sodium reduction goals.

We received requests for 90- and 30-day extensions of these comment periods, respectively. In general, the requests expressed concern that the current 90- and 150-day comment periods do not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance. Some requests mentioned a need for companies to review the sodium concentration in their products, to consider what technology might be needed to meet the sodium reduction 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.

Dated: August 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20780 Filed 8–29–16; 8:45 am]

BILLING CODE 4164–01–P

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.