4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1497]

Toxicological Principles for the Safety Assessment of Food Ingredients; Public Meeting on Updates and Safety and Risk Assessment Considerations; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting; request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notification of public meeting and request for comments that appeared in the Federal Register of October 30, 2014. The notification requested comments on certain topics related to our guidance titled "Toxicological Principles for the Safety Assessment of Food Ingredients," known less formally as the "Redbook". We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notification of public meeting and request for comments published October 30, 2014 (79 FR 64603). Submit either electronic or written comments by May 11, 2015.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA-2014-N-1497) for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or 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, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jeremiah Fasano, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1173, jeremiah.fasano@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 30, 2014 (79 FR 64603), we published a notification of public meeting and requested comments on certain topics related to the Redbook. The Redbook provides guidance to industry and other stakeholders (e.g., academia and other

regulatory groups) regarding the information used by FDA's Center for Food Safety and Applied Nutrition to evaluate the safety of food additives and color additives. The Redbook is intended to help interested parties understand FDA's expectations regarding:

- Determining the human exposure that will occur from the use of the ingredient in foods;
- Determining which toxicity studies are appropriate;
- Designing, conducting, and reporting the results of toxicity studies; and
- Submitting the information to FDA as part of a safety assessment.

Comments on the Redbook will inform our future efforts on what should be included, changed, or even excluded from the updated Redbook. We are interested in expanding the scope of the Redbook to emphasize the principles of safety and risk assessment that are shared across different regulatory contexts for foods and cosmetics, while still providing specific guidance for applying these principles in particular contexts such as the requirements for premarket safety submissions or for risk assessments conducted on foods and cosmetics already on the market.

We have received a request for a 90-day extension of the comment period for the notification of public meeting and request for comments. The request conveyed- concern that the current 90-day comment period (which would otherwise expire on February 9, 2015) does not allow sufficient time to develop meaningful or thoughtful responses to the notification of public meeting and request for comments.

We have considered the request and are extending the comment period for 90 days, until May 10, 2015. We believe that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying further action on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: January 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-01858 Filed 01/30/2015 at 8:45 am; Publication Date: 02/02/2015]