

made to OPPI on a reimbursement basis. OPPI has not submitted a request for reimbursement under the FY 2014 PADD grant award leaving the entire amount of the award unspent. It is unclear, then, how OPPI is exercising the P&A authorities and conducting P&A activities without utilizing the federal financial assistance.

Dated: January 27, 2015.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2015-01857 Filed 1-30-15; 8:45 am]

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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 1-30-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2031]

For Nominations on the Food Advisory Committee; Extension of Closing Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of closing date.

SUMMARY: The Food and Drug Administration (FDA) is extending the closing date for the notice that appeared

in the **Federal Register** of December 8, 2014. In the notice, FDA requested that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Food Advisory Committee (the Committee) for the Center for Food Safety and Applied Nutrition (CFSAN) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the Committee. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit letters of interests and nominations.

DATES: FDA is extending the closing date in the notice published December 8, 2014 (79 FR 72690). Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by February 27, 2015. Concurrently, nomination materials for prospective candidates should be sent to FDA by February 27, 2015.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Karen Strambler (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Karen Strambler, Office of Regulations, Policy, and Social Science, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Rm. 1C-016, College Park, MD 20740, 240-402-2589, karen.strambler@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. CFSAN Advisory Committee, Food Advisory Committee

The Committee reviews and evaluates emerging food safety, nutrition and other food- or cosmetic-related health issues that FDA considers of primary

importance for its food and cosmetics programs. The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food- or cosmetic-related issues; (2) the safety of food ingredients and new foods; (3) labeling of foods and cosmetics; (4) nutrient needs and nutritional adequacy; and (5) safe exposure limits for food contaminants. The Committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current curriculum vitae. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women, and men, members of all racial and ethnic groups and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: *January 26, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-01881 Filed 1-30-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0175]

Determination That LYMPHAZURIN (Isosulfan Blue) Injectable and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6223, Silver Spring, MD 20993-0002, 301-796-5418, Amy.Hopkins@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as