

Dated: July 10, 2012.

Ronald K. Lorentzen,
Acting Assistant Secretary for Import
Administration.

[FR Doc. 2012-17284 Filed 7-16-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. FDA-2012-F-0728]

Representative Edward J. Markey; Filing of Food Additive Petition

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Representative Edward J. Markey has filed a petition proposing that the food additive regulations be amended to no longer provide for the use of Bisphenol A (BPA)-based epoxy resins as coatings in packaging for infant formula because these uses have been abandoned. FDA expressly requests comments on the petitioner's request.

DATES: Submit either electronic or written comments by September 17, 2012.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-F-0728 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:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper or CD-ROM 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 Agency name and Docket No. FDA-2012-F-0728. 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 "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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vanee Komolprasert, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1217.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 2B4791) has been filed by Representative Edward J. Markey, House of Representatives, 2108 Rayburn House Office Building, Washington, DC 20515-2107. The petition proposes to amend the food additive regulations in § 175.300 (21 CFR 175.300) to no longer provide for the use of BPA-based epoxy resins as coatings in packaging for infant formula because these uses have been intentionally and permanently abandoned. BPA-based epoxy resins are formed by the reaction of 4,4'-isopropylendiphenol (i.e., BPA), and epichlorohydrin.

II. Abandonment

Under section 409(i) of the FD&C Act, FDA "shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations." FDA's regulations specific to administrative actions for food additives provide as follows: "The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive." (§ 171.130(a) (21 CFR 171.130(a))). These regulations further provide: "Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption

may justify its amendment or appeal. New data shall be furnished in the form specified in §§ 171.1 and 171.100 for submitting petitions." (§ 171.130(b)). Under these regulations, a petitioner may propose that FDA amend a food additive regulation if the petitioner can demonstrate that there are "old uses abandoned" for the relevant food additive. Such abandonment must be complete for any intended uses in the U.S. market. While section 409 of the FD&C Act and § 171.130 also provide for amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on safety, but is based on the fact that the regulatory authorization is no longer necessary because the use of the food additive has been abandoned.

Abandonment may be based on the abandonment of certain authorized food additive uses for a substance (e.g., if a substance is no longer used in certain product categories), or on the abandonment of all authorized food additive uses of a substance (e.g., if a substance is no longer being manufactured). If a petition seeks an amendment to a food additive regulation based on the abandonment of certain uses of the food additive, such uses must be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

The petition submitted by Representative Markey contains public information and information collected from a survey of the U.S. registered manufacturers of infant formula to support the petitioner's claim that all U.S. infant formula manufacturers have abandoned the use of BPA-based epoxy resins as coatings in all food contact packaging for infant formula. According to the petition, these companies accounted for 100% of the current infant formula market in the United States.

FDA expressly requests comments on the petitioner's request that FDA amend the food additive regulations to no longer permit the use of BPA-based epoxy resins as coatings in packaging for infant formula. For the purposes of this petition, FDA considers the use of BPA-based epoxy resins as coatings (as described in § 175.300(a)) in packaging of infant formula to mean a metal substrate (single use) or any suitable substrate (repeated use) being coated with BPA-based epoxy resins as a continuous film or enamel, serving as a functional barrier between the infant formula (powder or liquid) and the substrate. As noted, the basis for the proposed amendment is that the use of

BPA-based epoxy resins as coatings in packaging for infant formula has been permanently and completely abandoned. Accordingly, FDA requests comments that address whether these uses of BPA-based epoxy resins have been completely abandoned, such as information on whether infant formula packaging containing BPA-based epoxy resins as coatings is currently being introduced or delivered for introduction into the U.S. market. Further, FDA requests comments on whether the uses that are the subject of the petition (BPA-based epoxy resins as coatings in infant formula packaging) have been adequately defined. FDA is not aware of information that suggests continued use of BPA-based epoxy resins as coatings in packaging for powder or liquid infant formula. FDA is providing the public 60 days to submit comments. FDA anticipates that some interested persons may wish to provide FDA with certain information that they consider to be trade secret or confidential commercial information (CCI) that would be exempt under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552). Interested persons may claim information that is submitted to FDA as CCI or trade secret by clearly marking both the document and the specific information as "confidential." Information so marked will not be disclosed except in accordance with the Freedom of Information Act (5 U.S.C. 552) and FDA's disclosure regulations (21 CFR part 20). For electronic submissions to <http://www.regulations.gov>, indicate in the "comments" box of the appropriate docket that your submission contains confidential information. Interested persons must also submit a copy of the comment that does not contain the information claimed as confidential for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice.

FDA is not requesting comments on the safety of these uses of BPA-based epoxy resins as coatings because, as discussed previously, such information is not relevant to establishing abandonment as the basis of the proposed action. Any comments addressing the safety of BPA-based epoxy resins or containing safety information on these resins will not be considered in FDA's evaluation of this petition. Separate from FDA's consideration of this petition, FDA is actively assessing the safety of BPA (see 75 FR 17145, April 5, 2010; see also

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>).

FDA has determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. 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: July 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-17367 Filed 7-16-12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2012-0406; FRL-9699-2]

Approval and Promulgation of Air Quality Implementation Plans; Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a request submitted by the Indiana Department of Environmental Management on May 14, 2012, to revise the Indiana State Implementation Plan (SIP). The submission revises the Indiana Administrative Code (IAC) definition of "References to the Code of Federal Regulations," from the 2009 edition to the 2011 edition.

DATES: Comments must be received on or before August 16, 2012.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R05-OAR-2012-0406 by one of the following methods:

1. www.regulations.gov: Follow the on-line instructions for submitting comments.
2. *Email:* blakley.pamela@epa.gov.
3. *Fax:* (312) 692-2450.

4. *Mail:* Pamela Blakley, Chief, Control Strategies Section (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* Pamela Blakley, Chief, Control Strategies Section (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Charles Hatten, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6031, hatten.charles@epa.gov.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule, and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: June 27, 2012.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2012-17263 Filed 7-16-12; 8:45 am]

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