4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2016-F-1444]

Styrene Information and Research Center; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by the Styrene Information and Research Center (SIRC), requesting that we amend our food additive regulations to no longer provide for the use of styrene as a synthetic flavoring substance and adjuvant in food because these uses of styrene have been abandoned.

DATES: The food additive petition was filed on May 16, 2016. Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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-2016-F-1444 for "Styrene Information and Research Center; Filing of Food Additive Petition." 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: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1071.

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)), we are giving notice that we have filed a food additive petition (FAP 6A4817), submitted by SIRC, c/o Keller and Heckman LLP, 1001 G Street, NW., Suite 500 West, Washington, DC 20001. The petition proposes to amend § 172.515 (21 CFR 172.515) to no longer provide for the use of styrene (CAS Reg. No. 100-42-5) as a synthetic flavoring substance and adjuvant in food because these uses of styrene have been permanently abandoned.

II. Abandonment

Under section 409(i) of the FD&C Act, we "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." Our regulations specific to administrative actions for food additives provide that the Commissioner of Food and Drugs, on his own initiative or on the petition of any interested person, under 21 CFR part 10, 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 that 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 must be furnished in the form specified in 21 CFR 171.1 and 171.100 for submitting petitions (§ 171.130(b)). Under these regulations, a petitioner may propose that we 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 regulatory authorization is no longer necessary because the use of that 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 on behalf of SIRC contains public information and information collected from companies that produce styrene to support the petitioner's claim that styrene is no longer being manufactured, imported, or otherwise marketed for use as a synthetic flavoring substance and adjuvant in food in the U.S. market and that the manufacturers have abandoned the use of styrene for these uses. SIRC surveyed its membership, which contains over 95 percent of the current North American styrene industry, to verify that their members do not:

- Currently manufacture styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;
- currently import styrene for use as a synthetic flavoring substance and adjuvant in food into the United States;
- intend to manufacture or import styrene for use as a synthetic flavoring substance and adjuvant in food in the United States in the future; and
- currently maintain any inventory of styrene for sale or distribution into commerce that is intended to be marketed for use as a synthetic flavoring substance and adjuvant in food in the United States.

SIRC also has confirmed that no foreign manufacturers appear to be using or marketing styrene for use as a synthetic flavoring agent or adjuvant in food.

We expressly request comments on SIRC's request to amend § 172.515 of the food additive regulations to no longer permit the use of styrene as a synthetic flavoring substance and adjuvant in food. As noted, the basis for the proposed amendment is that the uses of styrene as a synthetic flavoring substance and adjuvant in food have been permanently abandoned. Accordingly, we request comments that address whether these uses of styrene have been completely abandoned, such as information on whether food containing styrene used as a synthetic flavoring substance and adjuvant are currently being introduced or delivered for introduction into the U.S. market. We are not currently aware of information that suggests continued use of styrene as a synthetic flavoring substance and adjuvant in food. We are providing the public with 60 days to submit comments. We anticipate that some interested persons may wish to provide us with certain information 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 us 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 and our 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.

We are not requesting comments on the safety of these uses of styrene because such information is not relevant to abandonment, which is the basis of the proposed action. We will not consider any comments addressing the safety of styrene or containing safety information on styrene in our evaluation of this petition.

We have 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.

Dated: June 9, 2016.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

[FR Doc. 2016-14107 Filed: 6/14/2016 8:45 am; Publication Date: 6/15/2016]