V. The Repeal of the Rule Is Not Intended To Preempt State Action for Deceptive or Unfair Acts or Practices Regarding Television Screen Size

To prevent what CTA characterized as the potential for ''a complicated patchwork quilt of inconsistent [state law] mandates,'' [42] it asked the Commission to issue an affirmative statement that by repealing the Rule it intends to preempt any state regulatory or enforcement actions regarding representations of television screen size.[43] The Commission declines to issue such a statement.

While the Commission concludes that a trade regulation rule for television screen measurement is no longer necessary, it retains its authority to address future unfair or deceptive practices relating to television screen measurement on a case-by-case basis.[44] Similarly, states have authority under analogous state laws. Therefore, the Commission's repeal of the Rule is not intended to preempt the states from taking regulatory or enforcement actions to prevent deception or unfairness concerning television screen measurement.

VI. Regulatory Flexibility Act and Regulatory Analysis

Under Section 22 of the FTC Act, 15 U.S.C. 57b–3, the Commission must issue a final regulatory analysis for a proceeding to amend a rule only when it: (1) Estimates that the amendment will have an annual effect on the national economy of $100 million or more; (2) estimates that the amendment will cause a substantial change in the cost or price of certain categories of goods or services; or (3) otherwise determines that the amendment will have a significant effect upon covered entities or upon consumers. The Commission determines that the repeal of the Rule will not have such effects on the national economy; on the cost of televisions; or on covered parties or consumers. The Rule repeal, rather than imposing any costs on covered parties or consumers, will eliminate any costs associated with complying with the Rule. Accordingly, the repeal of the Rule is exempt from Section 22's final regulatory analysis requirements.

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–612, requires that the Commission conduct an analysis of the anticipated economic impact of the amendment of a rule on small entities. The purpose of a regulatory flexibility analysis is to ensure that an agency considers the impacts on small entities and examines regulatory alternatives that could achieve the regulatory purpose while minimizing burdens on small entities. Section 605 of the RFA, 5 U.S.C. 605, provides that such an analysis is not required if the agency head certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities. The Commission concludes that the repeal of the Rule will not have a significant economic impact upon small entities because the Rule's repeal will eliminate any costs associated with complying with the Rule. Therefore, in the Commission's view, the repeal of the Rule will not have a significant or disproportionate impact on the costs of small entities that sell televisions. These entities appear to provide consumers with the screen size as measured by a television's manufacturer and that typically appears on a television's packaging. In addition, the Commission is not aware of any existing federal laws or regulations that address the measurement of television screens and that would conflict with the repeal of the Rule. Therefore, based on available information, the Commission certifies that repealing the Rule will not have a significant economic impact on a substantial number of small entities.

VII. Repeal of Rule

For the reasons stated in the preamble, and under the authority of 15 U.S.C. 57a, the Commission removes 16 CFR part 410.

List of Subjects in 16 CFR Part 410

Advertising, Electronic funds transfer, Television, and Trade practices.

By direction of the Commission, Commissioner Wilson not participating.

Donald S. Clark,

Secretary.

PART 410—[REMOVED]

■ Accordingly, under the authority of 15 U.S.C. 57a, the Commission removes 16 CFR part 410.

[FR Doc. 2018–21803 Filed 10–5–18; 8:45 am]

BILLING CODE 6750–01–P

enforcement, the Commission stated that should it find any future deception of the type that the Rule was intended to prevent, the Commission could address this deception through case-by-case enforcement).

[42] CTA–II at 9.

[43] CTA–II at 9–11.

[44] *See* n. 41, *supra.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2016–F–1444]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Styrene

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending the food additive regulations to no longer provide for the use of styrene as a flavoring substance and adjuvant for use in food because these uses have been abandoned. We are taking this action in response to a food additive petition submitted by the Styrene Information and Research Center (SIRC).

DATES: This rule is effective October 9, 2018. See section VIII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by November 8, 2018.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before November 8, 2018. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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

objection, that information will be posted on *https://www.regulations.gov.*

• If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, 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 ''Food Additives Permitted for Direct Addition to Food for Human Consumption; Styrene.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 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, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1071.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 15, 2016 (81 FR 38984), we announced that we 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 proposed to amend § 172.515 *Synthetic flavoring substances and adjuvants* (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 abandoned. Any use of styrene other than as a synthetic flavoring substance and adjuvant in food in accordance with § 172.515 was considered outside the scope of this petition.

II. Evaluation of Abandonment

Section 409(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(i)) states that we must by regulation establish the procedure for amending or repealing a food additive regulation and that this procedure must conform to the procedure provided in section 409 of the FD&C Act for the issuance 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))). The regulations further provide that any such petition must 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 repeal. New data must 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 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 United States 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 should 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 information collected from its members to support the petitioner's claim that styrene is no longer manufactured, imported, or otherwise marketed for use as a synthetic flavoring substance and adjuvant in food in the U.S. market and that industry has abandoned such use of styrene. Specifically, the petition contained information SIRC collected through surveying its membership, which contains over 95 percent of the current North American styrene industry, to verify that its members:

• Do not currently manufacture styrene for use as a synthetic flavoring substance and adjuvant in food in the United States;

• do not currently import styrene for use as a synthetic flavoring substance and adjuvant in food into the United States;

- do not 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
- do not 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 confirmed that no foreign manufacturers appear to be using or marketing styrene for use as a synthetic flavoring substance or adjuvant in food, based on information received from the Japan Styrene Industry Association, the European Chemical Industry Council, and contacts in China.

Additionally, SIRC consulted with the Flavor and Extract Manufacturers Association of the Unites States and received a determination confirming that the Flavor and Extract Manufacturers Association members no longer use or produce styrene as a synthetic flavoring substance or adjuvant in food. The Flavor and Extract Manufacturers Association also submitted to the docket for this petition data and information in support of the petition, which FDA reviewed and evaluated in making its decision on this petition. The Flavor and Extract Manufacturers Association is a national association of the U.S. flavor industry whose members include flavor manufacturers, flavor users, flavor ingredient suppliers, and others. Based on information provided from Flavor and Extract Manufacturers Association, its members manufacture more than 95 percent of all flavoring substances sold in the United States.

III. Comments on the Filing Notice

We provided 60 days for comments on the filing notice. We received two comments. For ease of reading, we preface each comment discussion with a numbered ''Comment,'' and the word ''Response'' appears before FDA's response. The number assigned is for organizational purposes only and does not signify any individual comment's value, importance, or order in which it was received. One comment expressed concerns about the timing of FDA action on SIRC's abandonment petition. This comment is summarized below, followed by FDA's response. The other comment supported SIRC's conclusions that the use of styrene as a synthetic flavoring substance or adjuvant in food has been abandoned.

(Comment 1) One comment requested that we not make a final decision on the petition until after we make a final decision on a food additive petition (FAP 5A4810) submitted in 2015 by several consumer groups asking us to remove styrene (and six other additives) from § 172.515 as a synthetic flavoring substance and adjuvant in food on the basis that it is not safe for use in food (Docket No. FDA–2015–F–4317). The comment stated that if we make a decision on the petition based on abandonment before making a decision on FAP 5A4810 based on safety, a company may conclude that the use of styrene is generally recognized as safe (GRAS) without notifying us. The comment also stated that making a decision based on abandonment ''leaves unresolved the safety issue . . . and encourages industry to only consider whether something is abandoned in order to preempt a safety decision.'' Further, the comment stated that FDA is statutorily required to regulate food additives and prevent the use of those that are unsafe and that FDA's failure to make a determination based on safety would fall short of FDA's statutory duty.

(Response 1) FDA disagrees. We are not required to make a final decision on FAP 5A4810 before the current petition. With regard to the assertion that FDA is required to make a safety determination and that failure to do so falls short of FDA's statutory duty, FDA has numerous responsibilities related to food additives. Each year, FDA receives and responds to hundreds of submissions under the various petition and notification programs we administer. Therefore, if the use of a food additive is no longer authorized in response to an abandonment petition, FDA may determine that it is neither necessary nor an efficient use of its limited resources to address safety arguments related to an abandoned use.

With regard to the comment's concern that a manufacturer may conclude that the use of styrene as a synthetic flavoring substance and adjuvant in food is GRAS without notifying us, we note that, for a substance to be GRAS based on scientific procedures, the scientific data and information about the use of a substance must be generally available and there must be general recognition among qualified experts that those data and information establish that the substance is safe under the conditions of its intended use (21 CFR 170.30). Prior approval as a food additive does not mean that the use of a substance is GRAS (see 81 FR 54960 at 54976, August 17, 2016). FDA encourages firms to seek our evaluation of any conclusion of GRAS status before they introduce the substance into the market. In the event that a manufacturer later wishes to reinstate the use of styrene as a synthetic flavoring substance and adjuvant in food, we would expect the manufacturer to seek re-authorization through submission of a food additive petition because this intended use was previously authorized under section 409 of the FD&C Act.

With regard to the assertion that an abandonment petition could be used by industry to preempt a safety determination by FDA, we have the discretion to make a safety determination regardless of whether there is an abandonment petition.

Elsewhere in this issue of the **Federal Register** we have published a final rule in response to FAP 5A4810 amending § 172.515 to no longer authorize the use of benzophenone, ethyl acrylate, eugenyl methyl ether, myrcene, pulegone, and pyridine as synthetic flavoring substances and adjuvants in food.

IV. Conclusion

FDA reviewed the data and information in the petition and other available relevant material to evaluate whether the use of styrene as a synthetic flavoring substance and adjuvant in food has been has been permanently and completely abandoned. Based on the available information, we have determined that the use of styrene as a synthetic flavoring substance and adjuvant in food has been abandoned. Therefore, we are amending § 172.515 to no longer provide for the use of styrene as a synthetic flavoring substance and adjuvant in food.

V. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

VI. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the June 15, 2016, **Federal Register** notice of petition for FAP 6A4817 (81 FR 38984). We stated that we had 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'' such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

§ 172.515 [Amended]

■ 2. Amend § 172.515(b) by removing the entry for ''Styrene.''

Dated: October 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21808 Filed 10–5–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172 and 177

[Docket No. FDA–2015–F–4317]

Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; notification of partial denial of petition.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is partially granting a petition submitted by the Breast Cancer Fund (now known as the Breast Cancer Prevention Partners), Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Consumers Union, Environmental Defense Fund, Environmental Working Group, Improving Kids' Environment, Natural Resources Defense Council, WE ACT for Environmental Justice, and Mr. James Huff, by amending the food additive regulations to no longer authorize the use of benzophenone, ethyl acrylate, eugenyl methyl ether, myrcene, pulegone, and pyridine as synthetic flavoring substances for use in food. We are taking this action because, despite FDA's scientific analysis and determination that these substances do not pose a risk to public health under the conditions of their intended use, the petitioners provided data demonstrating that these additives induce cancer in laboratory animals, and, as a result of this finding in animals, FDA cannot as a matter of law maintain the listing of these synthetic flavoring substances in the food additive regulations. Because of evidence that benzophenone causes cancer in animals, FDA also is amending the food additive regulations to no longer provide for the use of benzophenone as a plasticizer in rubber articles intended for repeated use in contact with food. FDA is denying as moot the portions of the petition proposing that the food additive regulations be amended to no longer authorize the use of styrene as a synthetic flavoring substance because this use has been permanently and completely abandoned. In addition, FDA is declining to act on the petitioners' request to issue a regulation to prohibit the use of these synthetic flavoring substances in food because that issue is not the proper subject of a food additive petition.

DATES: This rule is effective October 9, 2018. See section IX for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by November 8, 2018.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before November 8, 2018. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

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