4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2015-F-4317]

Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff; 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 Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff, proposing that the food additive regulations be amended to no longer authorize the use of seven listed synthetic flavoring food additives and to establish zero tolerances for the additives.

DATES: The food additive petition was filed on August 17, 2015. 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-2015-F-4317 for "Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff; 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 5A4810) submitted by the Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff, c/o Thomas Neltner, 1875 Connecticut Ave. NW., Suite 600, Washington, DC 20009. The petition proposes to amend § 172.515 (21 CFR 172.515), Synthetic flavoring substances and adjuvants, to no longer provide for the use of seven listed synthetic flavoring food additives and to establish zero tolerances for these additives.

The seven food additives that are the subject of this petition are as follows:

- Benzophenone (also known as diphenyl ketone) (CAS No. 119-61-9);

- Ethyl acrylate (CAS No. 140-88-5);
- Eugenyl methyl ether (also known as 4-allylveratrole or methyl eugenol) (CAS No. 93-15-2);
- Myrcene (also known as 7-methyl-3-methylene-1,6-octadiene) (CAS No. 123-35-3);
- Pulegone (also known as p-menth-4(8)-en-3-one) (CAS No. 89-82-7);
- Pyridine (CAS No. 110-86-1); and
- Styrene (CAS No. 100-42-5).

II. Amendment of § 172.515

In accordance with the procedures for amending or revoking a food additive regulation in § 171.130 (21 CFR 171.130), the petition asks us to amend § 172.515 to no longer provide for the use of these seven food additives as synthetic flavoring substances. Specifically, the petitioners contend that new data establish that these substances are carcinogenic and are, therefore, not safe for use in food under the Delaney Clause (section 409(c)(3)(A) of the FD&C Act), which provides that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. The petitioners cite, as evidence, conclusions by the National Toxicology Program, the International Agency for Research on Cancer, and the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment. The petitioners also include results from an observational epidemiology study in humans exposed to styrene and a number of long-term, animal feeding studies conducted on each of the seven additives to support their request. If we determine new data are available that establish these food additives induce cancer, then FDA will

amend § 172.515 to no longer provide for their use by publishing an amendment to the regulation in the Federal Register, as set forth in §§ 171.130 and 171.100 (21 CFR 171.100).

Although the petition proposes to amend only § 172.515 to no longer provide for the use of these seven synthetic flavoring substances, our action in response to the petition could affect other regulations which provide specifically for the use of these additives. Specifically, benzophenone is also approved for use as an indirect food additive, i.e., a plasticizer (21 CFR 177.2600(c)(4)(iv) diphenyl ketone). We note that some of these flavoring substances (e.g., ethyl acrylate, pyridine, styrene) are permitted for use by other food additive regulations and food contact notifications as reactants or manufacturing aids. Such uses are not the subject of these food additive regulations and food contact notifications, and as such, may not necessarily be affected if this petition results in a regulation.

III. Establish a Zero Tolerance

The petition also requests that FDA explicitly establish a zero tolerance for these seven substances in § 172.515. There is no statutory or regulatory provision for establishing a zero tolerance standard for flavoring food additives in § 172.515. We note, however, that 21 CFR part 189 permits FDA to prohibit by rulemaking the use of substances in human foods because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human foods. To the extent that a rulemaking under part 189 to prohibit the use of these seven substances in food satisfies the petitioner's request for a zero tolerance, we will consider, to the extent appropriate, whether such a rulemaking is necessary if this petition results in a regulation.

We also are reviewing the potential environmental impact of the petitioners' requested action. The petitioners have claimed a categorical exclusion from preparing an environmental

assessment or environmental impact statement under 21 CFR 25.32(m). In accordance with regulations issued under the National Environmental Policy Act (40 CFR 1506.6(b)), we are placing the environmental document submitted with the subject petition on public display at the Division of Dockets Management (see ADDRESSES) so that interested persons may review the document. If we determine that the petitioners' claim of categorical exclusion is warranted and that neither an environmental assessment nor an environmental impact statement is required, we will announce our determination in the Federal Register if this petition results in a regulation. If we determine that the claim of categorical exclusion is not warranted, we will place the environmental assessment on public display at the Division of Dockets Management and provide notice in the Federal Register announcing its availability for review and comment.

Dated: December 29, 2015.

Dennis M. Keefe,

Director, Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

[FR Doc. 2015-33011 Filed: 12/31/2015 8:45 am; Publication Date: 1/4/2016]