YIKUK, NV	FIX	(Lat. 41°59′05.16″ N, long. 114°51′49.12″ W)
BROPH, ID	WP	(Lat. 42°43′15.71″ N, long. 114°52′31.80″ W)

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Issued in Washington, DC, on January 2, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–00085 Filed 1–10–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2023–C–5679]

Filing of Color Additive Petition From Environmental Defense Fund, et al.; Request To Amend the Color Additive Regulations To Remove the Solvents Ethylene Dichloride, Methylene Chloride, and Trichloroethylene

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a color additive petition, submitted by Environmental Defense Fund, et al., proposing that the color additive regulations be amended to remove three specified solvents.

DATES: The color additive petition was filed on December 21, 2023. Either electronic or written comments must be submitted by March 11, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 11, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 comment, that information will be posted on *https://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 instructions 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 comments 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–2023–C–5679 for ''Filing of Color Additive Petition From Environmental Defense Fund, et al.; Request To Amend the Color Additive Regulations To Remove the Solvents Ethylene Dichloride, Methylene Chloride, and Trichloroethylene.'' Received comments, those filed in a timely manner (see DATES), 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, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comment 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.'' We will review this copy, including the claimed confidential information, in our 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Paulette M. Gaynor, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1192.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 4C0327), submitted by Environmental Defense Fund, Breast Cancer Prevention Partners, Center for Environmental Health, Environmental Working Group, and Lisa Lefferts, c/o Lisa Lefferts, Nellysford, VA 22958. The petition proposes that we amend §§ 73.1 (21 CFR 73.1, ''Diluents in color additive mixtures for food use exempt from certification''), 73.30 (21 CFR 73.30, ''Annatto extract''), 73.345 (21 CFR 73.345, ''Paprika oleoresin''), and 73.615 (21 CFR 73.615, ''Turmeric oleoresin'') to remove the use of three specified solvents.

The three solvents that are the subject of this petition are:

1. Ethylene dichloride (CAS No. 107–06–2);

2. Methylene chloride (CAS No. 75–09–2); and

3. Trichloroethylene (CAS No. 79–01–6).

II. Request To Amend 21 CFR Part 73

In accordance with the procedure in section 721(d) of the FD&C Act for issuance, amendment, or repeal of regulations, the petition asks us to amend §§ 73.1, 73.30, 73.345, and 73.615 to remove ethylene dichloride, methylene chloride, and trichloroethylene. Specifically, the petitioners state these substances have been found to induce cancer in humans or animals and, therefore, are not safe pursuant to section 721(b)(5)(B) of the FD&C Act (also referred to as the ''Delaney Clause''). The Delaney Clause provides, in relevant part, that no color additive shall be deemed safe for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary of Health and Human Services (Secretary) to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal.

The petition is available in the docket. We invite comments, additional scientific data, and other information related to the issues raised by this petition. If we determine that the available data justify amending §§ 73.1, 73.30, 73.345, and 73.615 to remove ethylene dichloride, methylene chloride, and trichloroethylene, we will publish our decision in the **Federal Register** in accordance with 21 CFR 71.20.

The petitioners have claimed that this action is categorically excluded under 21 CFR 25.32(m), which applies to an action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics. In addition, the petitioners have stated that, to their knowledge, no extraordinary circumstances exist (see 21 CFR 25.21). If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: January 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–00410 Filed 1–10–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172 and 173

[Docket No. FDA–2023–F–5684]

Filing of Food Additive Petition From Environmental Defense Fund, et al.; Request To Amend the Food Additive Regulations To Remove the Solvents Benzene, Ethylene Dichloride, Methylene Chloride, and Trichloroethylene

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a food additive petition, submitted by Environmental Defense Fund, et al., proposing that the food additive regulations be amended to remove four specified solvents.

DATES: The food additive petition was filed on December 21, 2023. Submit either electronic or written comments on the filing notice by March 11, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 11, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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- 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'').

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- For written/paper comments submitted to the Dockets Management Staff, 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–2023–F–5684 for ''Filing of Food Additive Petition from Environmental Defense Fund, et al.; Request To Amend the Food Additive Regulations To Remove the Solvents Benzene, Ethylene Dichloride, Methylene Chloride, and Trichloroethylene.'' Received comments, those filed in a timely manner (see DATES), 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, 240–402–7500.

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