4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2023-C-5679]

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; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the notification of petition, published in the *Federal Register* of January 11, 2024, announcing that we filed a color additive petition proposing that the color additive regulations be amended to remove three specified solvents. FDA is reopening the comment period to allow for the submission of any updated data and other information over the last two years.

DATES: FDA is reopening the comment period on the notification of petition published January 11, 2024 (89 FR 1856). Either electronic or written comments must be submitted by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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 comments, 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 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 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-C-5679 for "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; Reopening of the Comment Period." Received comments, 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, 240-402-7500.

- 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." 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: Alexandra Beliveau, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 240-402-2378, HFP-Policy@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of January 11, 2024 (89 FR 1856), FDA announced that we had filed a color additive petition proposing that we amend 21 CFR 73.1, "Diluents in color additive mixtures for food use exempt from certification"; 21 CFR 73.30, "Annatto extract"; 21 CFR 73.345, "Paprika oleoresin"; and 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 (Chemical Abstract Service (CAS) No. 107-06-2);
2. Methylene chloride (CAS No. 75-09-2); and
3. Trichloroethylene (CAS No. 79-01-6).

Interested persons were originally given until March 11, 2024, to comment on the filed color additive petition.

FDA is reopening the comment period to allow for the submission of any updated data and other information over the last two years. FDA is also seeking comment on what practical considerations food manufacturers would have in phasing out impacted uses if FDA were to grant this petition in part or in whole.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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