4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA-2023-N-0437]

Filing of Color Additive Petition from Center for Science in the Public Interest, et al.; Request to Revoke Color Additive Listing for Use of FD&C Red No. 3 in Food and Ingested Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Petition for Rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Center for Science in the Public Interest, et al., proposing that FDA repeal the color additive regulations providing for the use of FD&C Red No. 3 in foods (including dietary supplements) and in ingested drugs.

DATES: The color additive petition was filed on November 15, 2022. Either electronic or written comments must be submitted by [INSERT DATE 60 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 60 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 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-N-0437 for "Filing of Color Additive Petition from Center for Science in the Public Interest, et al.; Request to Revoke Color Additive Listing for Use of FD&C Red No. 3 in Food and Ingested Drugs." 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: Shayla West-Barnette, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1262.

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 3C0323), submitted by Center for Science in the Public Interest, Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Chef Ann Foundation, Children's Advocacy Institute, Consumer Federation of America, Consumer Reports, Defend Our Health, Environmental Defense Fund, Environmental Working Group, Feingold Association of the United States, Food & Water Watch, Healthy Babies Bright Futures, Life Time Foundation, Momsrising, Prevention Institute, Public Citizen, Public Health Institute, Public Interest Research Group, Real Food for Kids, Lisa Y. Lefferts, Linda S. Birnbaum, and Philip J. Landrigan, c/o Jensen Jose, 1250 I Street NW, Suite 500, Washington, DC 20005. The petition proposes that we repeal the color additive regulations for FD&C Red No. 3 in § 74.303 (21 CFR 74.303), which permits the use of FD&C Red No. 3 in foods (including dietary supplements), and § 74.1303 (21 CFR 74.1303), which permits the use of FD&C Red No. 3 in ingested drugs.

II. Repeal of §§ 74.303 and 74.1303

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 repeal §§ 74.303 and 74.1303 to no longer provide for the use of FD&C Red No. 3 in foods (including dietary supplements) and in ingested drugs, respectively. Specifically, the petitioners state that experimental data show that FD&C Red No. 3 induces cancer when fed to rats and that FDA concluded such in 1990. The petitioners also state that subsequent studies and reviews have reinforced FDA's conclusion. The petitioners cite, as evidence, data and information from the National Toxicology Program, the Joint Expert Committee on Food Additives, and the European Commission's Scientific Committee for Food (which was later replaced by the European Food Safety Authority). The petitioners also state that there is widespread exposure to U.S. consumers, particularly children, and that very young children have the highest exposures to the color additive. The petitioners cite the Delaney Clause (section 721(b)(5)(B) of the FD&C Act), which provides 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 petitioners state that the Delaney Clause obligates FDA to repeal the regulations for FD&C Red No. 3.

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 repealing §§ 74.303 and 74.1303 to no longer provide for the use of FD&C Red No. 3, 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) because this action would prohibit or otherwise restrict the use of a substance in food packaging. In addition, the petitioners have stated that, to their knowledge, no extraordinary circumstances exist. 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: February 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-03391 Filed: 2/16/2023 8:45 am; Publication Date: 2/17/2023]