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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Petition for rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the color additive petition for which we published a notice of filing in the *Federal Register* of February 17, 2023. In the notice, FDA requested comments on a filed color additive 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. We are taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the color additive petition for which a notice of filing was published in the *Federal Register* of February 17, 2023 (88 FR 10245). Either electronic or written comments must be submitted by May 18, 2023.

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 on May 18, 2023. 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-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 **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: 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: In the *Federal Register* of February 17, 2023 (88 FR 10245), we published a notice of filing of a color additive petition with a 60-day comment period. We explained that, under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379e(d)(1)), we were giving notice that we had 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 color additive petition proposes that we repeal the color additive regulations for FD&C Red No. 3 in 21 CFR 74.303, which permits the use of FD&C Red No. 3 in foods (including dietary supplements), and 21 CFR 74.1303, which permits the use of FD&C Red No. 3 in ingested drugs.

We have received a request for a 60-day extension of the comment period for the color additive petition The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a thoughtful response to the color additive petition.

FDA has considered the request and is extending the comment period for the color additive petition until May 18, 2023. We believe that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying a response to this petition.

We also clarify a statement in the notice of filing. In describing the petitioners' claim that the action they sought in their petition is categorically excluded under our environmental regulations at § 25.32 (21 CFR 25.32), we referred only to a categorical exclusion for food packaging (88 FR 10245 at 10246). The regulation we cited, § 25.32(m), categorically excludes an action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics.

Dated: March 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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