



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2017-C-1951]

Environmental Defense Fund, Earthjustice, Environmental Working Group, Center for Environmental Health, Healthy Homes Collaborative, Health Justice Project of Loyola University Chicago School of Law, Breast Cancer Fund, Improving Kids' Environment, Consumers Union, Natural Resources Defense Council, Consumer Federation of America, Learning Disabilities Association, Maricel Maffini, and Howard Mielke; Filing of Color 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 Environmental Defense Fund, Earthjustice, Environmental Working Group, Center for Environmental Health, Healthy Homes Collaborative, Health Justice Project of Loyola University Chicago School of Law, Breast Cancer Fund, Improving Kids' Environment, Consumers Union, Natural Resources Defense Council, Consumer Federation of America, Learning Disabilities Association, Maricel Maffini, and Howard Mielke, proposing that FDA repeal the color additive regulation providing for the use of lead acetate in cosmetics intended for coloring hair on the scalp.

DATES: The color additive petition was filed on February 24, 2017. Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE

FEDERAL REGISTER]. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight 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 postmarked or the delivery service acceptance receipt is on or before that date.

ADDRESSES: You may submit comments as follows:

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 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-2017-C-1951 for "Environmental Defense Fund, Earthjustice, Environmental Working Group, Center for Environmental Health, Healthy Homes Collaborative, Health Justice Project of Loyola University Chicago School of Law, Breast Cancer Fund, Improving Kids' Environment, Consumers Union, Natural Resources Defense Council, Consumer Federation of America, Learning Disabilities Association, Maricel Maffini, and Howard Mielke; Filing of Color Additive Petition." 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 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 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 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 docket, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.gpo.gov/fdsys/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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1075.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 7C0309), submitted by the Environmental Defense Fund, Earthjustice, Environmental Working Group, Center for Environmental Health, Healthy Homes Collaborative, Health Justice Project of Loyola University Chicago School of Law, Breast Cancer Fund, Improving Kids' Environment, Consumers Union, Natural Resources Defense Council, Consumer Federation of America, Learning Disabilities Association, Maricel Maffini, and Howard Mielke, c/o Thomas Neltner, 1875 Connecticut Ave. NW., Suite 600, Washington, DC 20009. The petition proposes that we repeal the color additive regulation for lead acetate in § 73.2396 (21 CFR 73.2396), which permits the use of lead acetate in cosmetics intended for coloring hair on the scalp only, subject to certain restrictions.

II. Repeal of § 73.2396

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 § 73.2396 to no longer provide for the use of lead acetate in cosmetics intended for coloring hair on the scalp. Specifically, the petitioners contend that new data, available since we issued § 73.2396 in 1980 (45 FR 72112, October 31, 1980), demonstrate that lead acetate: (1) Is readily absorbed through human skin; (2) once absorbed, is transported to various organs, including the brain, and into extracellular fluid compartments; (3) has been designated as "reasonably anticipated to be a human carcinogen" based on evidence of carcinogenicity in experimental animals; (4) has other adverse health effects including neurotoxicity; and (5) there is no safe level of exposure to lead. The petitioners cite, as evidence, conclusions by the National Toxicology Program, the Centers for Disease Control and Prevention, the Environmental Protection Agency, and decisions related to

lead and lead compounds by other national regulatory agencies, including Health Canada. The petitioners claim that there is no longer a reasonable certainty of no harm from the use of lead acetate for coloring hair on the scalp.

We invite comments and additional scientific data and other information related to the issues raised by this petition. If we determine that the available data justify repealing § 73.2396 to no longer provide for the use of lead acetate, we will publish our decision in the Federal Register in accordance with 21 CFR 71.20.

We also are reviewing the potential environmental impact of the petitioners' requested action. The petitioners claim a categorical exclusion from preparing an environmental assessment or environmental impact statement under 21 CFR 23.32(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 environmental impact statement is required, we will announce our determination in the Federal Register if this petition results in the repeal of § 73.2396. 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: March 29, 2017.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

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