

• **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 dockets, 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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DEPARTMENT OF STATE

22 CFR Part 96

[Public Notice: 9940]

RIN 1400-AD91

Intercountry Adoptions

AGENCY: Department of State.

ACTION: Proposed rule; notice of withdrawal.

SUMMARY: The Department of State (Department) published a notice of proposed rulemaking (NPRM) on September 8, 2016, proposing to amend its regulations implementing the 1993 Hague Convention on Protection of Children and Co-operation in Respect of Intercountry Adoption and the Intercountry Adoption Act of 2000. 81 FR 62322. The Department hereby withdraws that action. The comments provided in response to the NPRM will be considered in drafting a new rule, which is expected to be published later this year.

DATES: September 8, 2016.

FOR FURTHER INFORMATION CONTACT: Trish Maskew, (202) 485-6024.

Theodore “Ted” R. Coley

Acting Deputy Assistant Secretary, Overseas Citizen Services, Bureau of Consular Affairs, U.S. Department of State.

[FR Doc. 2017-06558 Filed 4-3-17; 8:45 am]

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