

(a) Effective Date

This AD is effective December 5, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Pratt & Whitney Division (PW) PW4074D, PW4077D, PW4084D, PW4090, and PW4090-3 turbofan engines with low-pressure compressor (LPC) fan hub, part number (P/N) 51B821 or P/N 52B521, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by low-cycle fatigue analysis techniques, updated by the engine manufacturer, which indicated certain LPC fan hubs could crack before their published life limit. We are issuing this AD to prevent failure of the LPC fan hub. The unsafe condition, if not addressed, could result in uncontained hub release, damage to the engine, and damage to the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) After the effective date of this AD, perform a fluorescent penetrant inspection (FPI) and an eddy current inspection (ECI) of the LPC fan hub the next time the engine is separated at the M-flange and the LPC fan hub has accumulated 2,000 or more flight cycles since the last FPI and ECI.

(2) Thereafter, perform an FPI and an ECI of the LPC fan hub every time the engine is separated at the M-flange and the LPC fan hub has accumulated 2,000 or more flight cycles since the last LPC fan hub ECI and FPI.

(3) Use the Accomplishment Instructions, Step No. 11, in PW Alert Service Bulletin PW4G-112-A72-351, dated February 22, 2018, to do the ECI.

(4) If a crack is found during the inspections required by paragraphs (g)(1) or (2) of this AD, remove the LPC fan hub from service before further flight and replace with a part eligible for installation.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local flight standards district office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (i) of this AD. You may email your request to: ANE-AD-AMOC@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager

of the local flight standards district office/certificate holding district office.

(i) Related Information

For more information about this AD, contact Jo-Ann Theriault, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7105; fax: 781-238-7199; email: jo-ann.theriault@faa.gov.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Pratt & Whitney Division Alert Service Bulletin PW4G-112-A72-351, dated February 22, 2018.

(ii) [Reserved.]

(3) For service information identified in this AD, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06118; phone: 800-565-0140; fax: 860-565-5442.

(4) You may view this service information at FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781-238-7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Burlington, Massachusetts, on October 25, 2018.

Robert J. Ganley,

Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2018-23712 Filed 10-30-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

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

Termination of Listing of Color Additive Exempt From Certification; Lead Acetate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to no longer provide for the use of lead acetate in cosmetics intended for coloring hair on the scalp because new

data available since lead acetate was permanently listed demonstrate that there is no longer a reasonable certainty of no harm from the use of this color additive. This action is in response to a color additive petition filed 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.

DATES: This rule is effective December 3, 2018. See section XIII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by November 30, 2018.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before November 30, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 30, 2018. Objections 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.

Electronic Submissions

Submit electronic objections in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an objection with confidential information that you do not wish to be made available to the

public, submit the objection 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 objections 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-2017-C-1951 for “Termination of Listing of Color Additive Exempt From Certification; Lead Acetate.” Received objections, 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.

- *Confidential Submissions*—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections 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.gpo.gov/>

[fdsys/pkg/FD-2015-09-18/pdf/2015-23389.pdf](https://www.regulations.gov/pkgs/FD-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.

FOR FURTHER INFORMATION CONTACT:

Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 240-402-1075.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of April 4, 2017 (82 FR 16321), FDA announced that we filed a color additive petition (CAP 7C0309) (the 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 (petitioners), c/o Mr. Tom Neltner, 1875 Connecticut Ave. NW, Suite 600, Washington, DC 20009. The petition requested that we repeal the regulation at § 73.2396 (21 CFR 73.2396) to no longer provide for the safe use of lead acetate in cosmetics intended for coloring hair on the scalp. The notice of petition gave interested parties until June 5, 2017, to submit comments on the filed color additive petition.

II. Background and Regulatory History of Lead Acetate as a Color Additive

The color additive lead acetate (the trihydrate of lead (2+) salt of acetic acid; CAS No. 6080-56-4) has been in use in cosmetic hair dyes for many years. Under the provisions of the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA published a notice on December 10, 1963 (28 FR 13374), stating that metallic salts (including lead acetate) used as hair colorings are color additives within the meaning of the FD&C Act. Because metallic salts, including lead acetate, were in use as color components in hair dye prior to the Color Additive Amendments of

1960, they were provisionally listed for this use on an interim basis under the transitional provisions of the Color Additive Amendments (38 FR 7006, March 15, 1973). Subsequently, FDA gave interested persons until July 30, 1973, to submit petitions proposing appropriate permanent listings of any metallic salts as coloring components of hair dye not presently listed for such use (38 FR 2996, January 31, 1973). On May 18, 1973, FDA received a color additive petition (CAP 3C0107) from the Committee of the Progressive Hair Dye Industry requesting the permanent listing of lead acetate as a color additive in cosmetic hair dyes. FDA published a notice of filing of the petition in the **Federal Register** of June 29, 1973 (38 FR 17260). While the petition was under review, FDA added lead acetate to the codified provisional list for use as a color component in hair dye on March 13, 1974 (39 FR 9657), with a closing date of December 31, 1974. The closing date for the provisional listing of lead acetate was postponed periodically pending the performance, completion, and evaluation of toxicological and absorption studies. A final rule in the **Federal Register** of March 3, 1978 (43 FR 8790), details each postponement up to that time, and subsequent postponements of the closing date for the provisional listing of lead acetate were published in the **Federal Register** on January 2, 1979 (44 FR 45), March 6, 1979 (44 FR 12169), August 31, 1979 (44 FR 51216), February 22, 1980 (45 FR 11799), June 24, 1980 (45 FR 42255), and December 30, 1980 (45 FR 85725).

In evaluating the scientific data submitted in CAP 3C0107, FDA determined that the following issues required resolution to enable FDA to evaluate the petition and determine the conditions of safe use of lead acetate: (1) Whether absorption and systemic distribution of lead acetate from hair dyes would occur, because the available scientific data did not establish conclusively that lead acetate from hair dyes was transdermally absorbed through the scalp; (2) whether lead acetate is carcinogenic in humans, because it had been established through animal feeding studies that lead is a carcinogen in rats and mice; (3) whether the human epidemiological data available are equivocal; and (4) which of the “Delaney” anticancer clauses in section 721(b)(5)(B) of the FD&C Act (21 U.S.C. 379e(b)(5)(B)) is applicable to this use of lead acetate (45 FR 72112, October 31, 1980).

To resolve the issue of whether lead acetate would be transdermally absorbed through the scalp, FDA requested that the petitioner perform a

definitive percutaneous absorption study (42 FR 62497 at 62499, December 13, 1977). Results from a 1978 radioactive tracer skin lead absorption study, using human volunteers, was submitted by the petitioner of CAP 3C0107 for FDA review and later published by Moore et al. (Ref. 1). The results of the percutaneous absorption study showed that lead acetate in hair dye is absorbed through human skin and that users who apply the hair dye as often as twice per week have an estimated average daily lead absorption of 0.3 microgram (μg). FDA considered the absorbed amount of lead acetate from hair dye to be “miniscule” when compared to the average person’s blood lead level from background sources and concluded that the resulting increase in exposure would have no discernible increase on the steady-state blood lead level reported to be approximately 17 μg per deciliter ($\mu\text{g}/\text{dL}$) (45 FR 72112 at 72114).

FDA also considered the applicability of the Delaney Clause (section 721(b)(5)(B) of the FD&C Act) in determining whether lead acetate could be permanently listed, considering the evidence that lead was shown to be a carcinogen in animal feeding studies. The Delaney Clause consists of two parts. The first part (section 721(b)(5)(B)(i) of the FD&C Act) pertains specifically to ingested color additives. The second part (section 721(b)(5)(B)(ii) of the FD&C Act) applies to non-ingested color additives. FDA explained in the 1980 final rule that because the first part of the Delaney Clause (section 721(b)(5)(B)(i) of the FD&C Act) is limited to uses that will or may result in ingestion, it does not apply to the use of lead acetate in hair dye applied on the scalp. FDA then considered the applicability of the non-ingestion clause, which states that a color additive shall be deemed unsafe, and shall not be listed, for any use that will not result in ingestion or any part of such additive, if evaluation of the safety of additives for such use or after other relevant exposure of man or animal to such additive, it is found by the Secretary of Health and Human Services (Secretary) to induce cancer in man or animal. After evaluation of the available relevant scientific evidence, FDA concluded that the available animal feeding studies were not relevant to the use of lead acetate in hair dye. FDA also concluded that the scientific data submitted were not sufficient to substantiate a direct correlation between dermal exposure to lead and human carcinogenicity. Additionally, FDA considered two carcinogenicity risk assessments based

on the percutaneous absorption data submitted in the CAP, one prepared by Dr. Richard Wilson of Harvard University (on behalf of the petitioner of CAP 3C0107) and the other prepared by FDA personnel, which concluded a 1:18 million and 1:12 million chance of developing cancer, respectively, by using lead acetate containing hair dye. FDA determined that these assessments supported the conclusion that any carcinogenic risk likely to result from use of lead acetate-containing hair dye could not be considered significant in terms of public health protection (45 FR 72112 at 72116).

Based on the evaluation of the available data, FDA concluded that lead acetate was safe for use in hair dyes intended for use on the scalp. On October 31, 1980, FDA approved the petition and permanently listed lead acetate in § 73.2396 as a color additive for the safe use in cosmetics for coloring hair on the scalp at levels up to 0.6 percent (weight to volume) lead, subject to certain restrictions and labeling requirements (45 FR 72112). As a condition of safe use, the regulation in § 73.2396 specifies that lead acetate hair dye must contain a cautionary statement.

III. Regulation of Color Additives

The FD&C Act provides a process through which any person who wishes to use a color additive in or on food, drugs, devices, or cosmetics, may submit a petition proposing the issuance of a color additive regulation listing such use with supporting information. A color additive petition also may be submitted to propose the amendment or repeal of any existing color additive regulation (see section 721(b)(5)(C) and (d) of the FD&C Act). In response to a color additive petition, FDA may issue a regulation listing a color additive for use in or on food, drugs, devices, or cosmetics only if it determines that the additive is suitable and safe for such use (see section 721(b)(2)(A) of the FD&C Act). FDA’s determination that a color additive is safe means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended condition of use of the color additive (21 CFR 170.3(i)). This is referred to as the “general safety clause” for color additives. In addition, the Delaney Clause, under section 721(b)(5)(B)(i) of the FD&C Act, states that a color additive shall be deemed unsafe for any use that will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary,

after tests that are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal. To determine whether a color additive is safe under the general safety clause, the FD&C Act requires FDA to consider, among other relevant factors: (1) Probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or devices, or cosmetics because of the use of the additive; (2) cumulative effect, if any, of such additive “in the diet of man or animals,” taking into account the same or any chemically or pharmacologically related substance or substances in such diet; and (3) safety factors recognized by experts “as appropriate for the use of animal experimentation data” (see section 721(b)(5)(A) of the FD&C Act). For FDA to grant a petition that seeks repeal of a color additive regulation based upon new data concerning the safety of the color additive, such data must be adequate for FDA to conclude that there is no longer a reasonable certainty of no harm for the intended use of the color additive or that it must be deemed unsafe under the Delaney Clause.

IV. Petitioners’ Argument for Repeal of § 73.2396

In accordance with the procedure in section 721(d) of the FD&C Act for the issuance, amendment or repeal of regulations, the current color additive petition (CAP 7C0309) requests that FDA repeal the regulation for lead acetate in § 73.2396. The petitioners assert the following in support of their proposal (the petition, at pages 5 through 15):

1. “Toxicological evidence since 1980 shows there is no safe level of exposure to lead compounds,” and the “scientific evidence substantiating a direct correlation between lead exposure and human carcinogenicity is now sufficiently strong for FDA to conclude that lead acetate is unsafe pursuant to the Delaney Clause in 21 U.S.C. 379e(b)(5)(B).”

2. “FDA’s 1980 decision rested primarily on a single industry study” that had “serious flaws.”

3. “Exposure evidence since 1980 shows that skin absorption of lead acetate may be more significant than FDA considered.”

4. “Overall exposure to lead in the United States has dropped since 1980 so FDA’s conclusion that the exposure was insignificant is no longer valid.”

5. “Post-1980 evidence indicates that lead acetate is likely to be ingested from typical use.”

6. “Canada and Europe found the use of lead acetate as a color additive to be unsafe.”

Based on these arguments, the petitioners assert that the evidence available since lead acetate’s permanent listing in 1980 demonstrates that there is no longer a reasonable certainty that no harm would result from the use of lead acetate in hair dyes, and, therefore, the regulation authorizing this use as a color additive should be repealed. The petitioners submitted *in vitro* and *in vivo* nonclinical and clinical peer-reviewed publications, monographs, and general reports from associations and government agencies to support their assertions.

In section V that follows, FDA provides assessments of the petitioners’ assertions and their supporting information. FDA’s review, assessment, and evaluation of the petition are detailed in our two review memoranda (Refs. 2 and 3). In FDA’s review of the petition, we considered relevant studies and publications on lead and lead compounds, including lead acetate.

V. Review of the Petition

A. Petitioners’ Assertion No. 1

“Toxicological evidence since 1980 shows there is no safe level of exposure to lead compounds,” and “scientific evidence substantiating a direct correlation between lead exposure and human carcinogenicity is now sufficiently strong for FDA to conclude that lead acetate is unsafe pursuant to the Delaney Clause in 21 U.S.C. 379e(b)(5)(B).” To support this assertion, the petition cites “evidence with respect to lead acetate as a carcinogen,” including that the National Toxicology Program (NTP) has designated lead and lead compounds to be “reasonably anticipated to be a human carcinogen” based on “limited evidence in humans, and sufficient evidence of carcinogenicity in experimental animals.” The petition also cites “evidence of health effects other than cancer,” specifically that lead (as elemental lead and lead compounds, including lead acetate) “has other adverse effects across multiple systems at low levels,” “is a potent neurotoxin with no safe level of exposure for children,” and “is particularly harmful to pregnant women.” The petition also provides toxicological monographs, profiles, and reports on lead and lead compounds available since 1980 to support their view that lead acetate applied to the scalp is not safe.

The information provided in the petition to support their assertion that there is no safe level of exposure to lead

and its compounds includes reports and publications by government agencies and professional organizations, including an NTP monograph on Health Effects of Low-Level Lead (2012), Centers for Disease Control and Prevention (CDC) reports on lead (2009, 2015), Agency for Toxic Substances and Disease Registry (ATSDR) toxicology profile for lead (2007), an article on the Prevention of Childhood Lead Toxicity from the American Academy of Pediatrics Council on Environmental Health (2016), Environmental Protection Agency’s Integrated Risk Information System Chemical Assessment Summary on lead and lead compounds, and an abstract of the risk assessment of lead acetate conducted by Health Canada (2008). The petitioners also provide abstracts to published *in vivo* and *in vitro* animal and human studies, and links to the 2014 NTP report on carcinogenicity from exposure to lead and its compounds, including lead acetate.

FDA Assessment: FDA reviewed the peer-reviewed publications and monographs provided in the petition and other relevant information in our evaluation of the safety of the use of lead acetate in hair dyes (Ref. 2) and agrees with the petitioners that there is no evidence available at this time to determine a safe level of exposure to lead or lead compounds intentionally used as a color additive in hair dyes.

The toxicologic effects of lead exposure have been well-documented, and FDA has taken several actions to protect the public from exposure to lead in FDA regulated products, including prohibiting the use of tin-coated lead foil capsules on wine bottles (61 FR 4816, February 8, 1996 (now codified at 21 CFR 189.301)) and prohibiting the use of lead-soldering in food cans (60 FR 33106, June 27, 1995 (now codified at 21 CFR 189.240)) (see also 58 FR 33860 at 33864 through 33866, June 21, 1993 (discussing the health effects of adult exposure to lead); and see generally <https://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm2006791.htm> and <https://www.fda.gov/Cosmetics/ProductsIngredients/PotentialContaminants/ucm388820.htm> (identifying other actions by FDA’s Center for Food Safety and Applied Nutrition concerning both childhood and adult exposure to lead in food, food containers, and cosmetics)).

The risks of lead exposure are particularly high *in utero*, infancy, and in early childhood; CDC has stated that there is no safe blood lead level in children, and that even low levels of lead in blood have been shown to affect IQ, ability to pay attention, and

academic achievement (Ref. 4). As part of its program to prevent childhood lead poisoning, CDC has recommended 5µg/dL as the reference blood lead level to identify children who have been exposed to lead and who require case management (Ref. 4).

Lead exposure also poses significant health risks to adults (Refs. 5 and 6). These risks include hypertension, peripheral nerve dysfunction, and red blood cell protoporphyrin elevation (see 58 FR 33860 at 33864). A growing body of evidence indicates that adults, like children, may experience adverse health impacts from exposure to levels of lead lower than those previously believed to be harmful. For example, in 2012, the NTP provided evidence of adverse effects of exposure to low levels of lead (less than 10 µg/dL) in adult humans based on epidemiological evidence. The NTP concluded that there is sufficient evidence for decreased glomerular filtration rate (in the kidney) in adults and reduced fetal growth in pregnant women at blood lead levels less than 5 µg/dL; increased blood pressure, hypertension, and essential tremor in adults at blood lead levels less than 10 µg/dL; and adverse changes in sperm parameters in men, as well as increased time to achieve pregnancy, at blood lead levels greater than or equal to 15–20 µg/dL (Ref. 2). In 2011, the Joint Food and Agriculture/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA) withdrew the previously established Provisional Tolerable Weekly Intake (PTWI) for lead and concluded that it was not possible to establish a new PTWI that would be considered health protective (Ref. 7). Additionally, the U.S. Environmental Protection Agency has set the maximum contaminant level goal for lead in drinking water at zero (Ref. 8). Regarding the information provided in the petition on the carcinogenicity of lead, we discuss the relevance of this information to FDA’s decision on this petition in section VII.

B. Petitioners’ Assertion No. 2

“FDA’s 1980 decision rested primarily on a single industry study” by Moore et al. (Ref. 1) that had “serious flaws.” The petitioners contended that results from test conditions with higher absorption values, *e.g.*, scratched skin, were excluded in the final analysis, while those from test conditions that resulted in lower absorption values *e.g.*, “wet” and “cream” applications, were all included. The petitioners also noted that Moore et al. excluded all the results of the 24-hour “whole body” count and relied only on the 12-hour data after deciding that the increased absorption

from the 12 to 24 hours' measurements reflected "mechanical damage" from washing the test substance from the skin after 12 hours. The petitioners stated that the 24-hour "non-scratch" average absorption was two times greater than the 12-hour average. Additionally, the petitioners stated that Moore et al. may have only measured a proportion of the lead absorbed because in calculating the "whole-body" count they assumed that the transport and distribution of lead acetate through the skin is the same path as an intravenous solution of a known quantity of lead chloride used to establish the relationship between radioactivity in the calf region and the whole body, which the petitioners claim is an assumption that more recent studies call into question. The petitioners also questioned some assumptions made by Moore et al., claiming no references were cited to support these assumptions (e.g., that 6 milliliters (ml) of the lead acetate formulation is normally applied, of which 0.18 ml would reach the scalp, and 612 µg of lead would reach the scalp per hair dye application). The petitioners noted that instructions for use included in lead acetate hair dye packages do not typically specify amount to be applied to hair and that the amount applied would vary depending on the amount of hair.

FDA Assessment: We considered the deficiencies claimed by the petitioners with the percutaneous absorption study conducted by Moore et al. and conducted our own re-evaluation of that study (details in Ref. 2). We agree with the petitioners that the study conducted by Moore et al. may not have fully accounted for all the lead that may have been absorbed and localized in extracellular fluid compartments, such as saliva and sweat. Although the approach of estimating whole body uptake of lead based on measured activity in the calf region may have partially captured lead in these extracellular fluids, newer data suggest that looking at blood lead levels alone underestimates exposure to lead that would have localized in other compartments (Ref. 2).

Regarding the assertion that Moore et al. did not use the "worst-case scenario" by excluding in its final analysis results from whole-body monitoring collected from 12 to 24 hours, results from the 24-hour "non-scratch" whole-body monitoring data, and results from the scratched skin scenario, and including results from test conditions that resulted in lower absorption values (e.g., "wet" and "cream" applications), we agree that this may have resulted in limiting the average absorption values.

Regarding the assertion that some assumptions made by Moore et al. are unsupported (e.g., that 6 ml of the lead acetate formulation is normally applied, of which 0.18 ml would reach the scalp, and 612 µg of lead would reach the scalp per hair dye application), we note that although these assumptions may not reflect a worst-case use scenario, there is a study that was submitted in support of the petition for permanently listing lead acetate (CAP 3C0107) that evaluated the amount of lead acetate that reached the scalp on human subjects from application of a known volume of the hair dye that was characterized in the study as a typical application volume. Results from that study showed that the average amount of lead acetate that reaches the scalp from application of 7 ml of hair dye is approximately 3 percent of the amount applied.

As stated, we also conducted our own re-evaluation of the study by Moore et al. and identified the following deficiencies that we believe may have resulted in underestimation of lead exposure (Ref. 2):

(1) The study was conducted with formulations containing 6 millimole per liter (mmol/L) or 9 mmol/L lead acetate (equivalent to 0.12 or 0.18 percent lead), respectively, which are three to five times lower than the approved maximum use level (0.6 percent lead) in hair dyes.

(2) The ages of the eight male test subjects ranged from 20 to 35 years. FDA notes that most people who use lead acetate-containing hair dye products would typically be age 50 years or older. The subjects were therefore not considered representative of the targeted older population. This is important because the skin in older people is different from the skin in younger people.

(3) The test formulation was applied to the skin on the forehead of subjects, whereas lead acetate-containing hair dye is intended to be applied to hair on the scalp. FDA notes that there are well documented differences in the composition and functionality of skin tissue from the scalp and skin tissue from other regions of the body, including the forehead (Ref. 2). For example, scalp skin tissue is thicker and carries more blood than other skin tissue. Thus, applying the test substance to the forehead and non-scalp skin, like the forehead, to assess percutaneous absorption, may not mimic absorption through the scalp.

(4) The test formulation(s) were reportedly applied to a skin surface area of 8 to 10 square centimeters (cm²) on the forehead. FDA notes that lead

acetate-containing hair dye is intended to be applied to the full scalp that has a skin surface area of approximately 580 cm². Applying the test formulation to a surface area substantially less than 580 cm² is not representative of the intended condition of use. Therefore, using a surface area of 8 to 10 cm² likely yielded results that underestimated the percentage of lead acetate that was transdermally absorbed. Additionally, test results obtained from applying the formulation to a small surface area on the forehead would also affect the accuracy of extrapolation to account for the entire surface area of the scalp.

(5) The test formulations applied to the forehead were removed by washing with soap 12 hours after application. FDA notes that the 12-hour application period in the Moore et al. study may be too short to assess the full extent of percutaneous absorption of lead acetate under the intended conditions of use, which in some cases could remain on the scalp for 24 hours or longer thereby increasing the amount of lead percutaneously absorbed.

C. Petitioners' Assertion No. 3

"Exposure evidence since 1980 shows that skin absorption of lead acetate may be more significant than FDA considered." To support this assertion, the petitioners provide several peer-reviewed studies published since 1980, which they claim demonstrate that the capacity of the skin to absorb lead is more significant than FDA estimated in 1980. The studies included a wide-ranging collection of occupational exposures to in vivo (human and animal) and in vitro (using human or animal skin) testing.

FDA Assessment: The petitioners did not provide data on dermal absorption of lead acetate generated under the intended use conditions for hair dye products and did not provide an updated estimated exposure that would result from typical chronic use of lead acetate-containing hair dyes. However, to support their assertion that skin absorption of lead acetate may be greater than FDA previously estimated, the petitioners provided information that raised valid scientific questions about the adequacy of the study that FDA relied on to support the listing of lead acetate in § 73.2396. The petition cited peer-reviewed publications describing nonclinical (in vitro and in vivo) and clinical studies to demonstrate dermal absorption of lead and lead compounds, including lead acetate. FDA reviewed these publications and other available pertinent publications and information on the dermal absorption of lead and lead acetate (Ref. 2). Following the

review, FDA concluded that the submitted publications demonstrate that dermally applied lead acetate and other lead-containing compounds penetrate human and animal skin, and report absorption of dermally applied lead and lead compounds ranging from 0.018 to 29 percent (the latter being under conditions of occlusion). In addition, some of the studies show that dermally absorbed lead distributes to extracellular fluid compartments including sweat and saliva, which the petitioners argued may contribute to an increase in lead exposure that was not previously accounted for in the Moore et al. publication (Ref. 2). However, we note that not all studies evaluated lead acetate, and not all the study designs were adequate. For example, the number of test subjects used in some studies was not adequate to ensure sufficient statistical power of the study, while in many studies, the surface area, location of application of the test substance, and the amount applied did not appropriately reflect the intended conditions of use of lead acetate to color hair on the scalp. These limitations made interpretation of the combined results from these studies difficult, and FDA was unable to reconcile all the reported findings related to absorption percentages and the lead levels claimed to be present in sweat and saliva (Ref. 2).

Given the deficiencies identified by FDA in the study by Moore et al. that may have resulted in underestimation of the amount of lead acetate that is transdermally absorbed, FDA chose to conduct further research on potential absorption from this use. FDA used in silico modeling (ConsExpo, Netherlands (Ref. 9)) to predict the percentage of dermal absorption of lead that may result from application of lead acetate hair dye to hair on the full human scalp based on empirically derived diffusion coefficients. Contrary to the 0 to 0.3 percent lead absorption reported by Moore et al. (Ref. 1), the results from our in silico modeling predicted higher levels of lead absorption from dermal application of lead acetate hair dyes containing 0.6 percent lead to the entire scalp under the intended conditions of use (Ref. 2).

To calculate the maximum amount of lead that could be absorbed, FDA utilized its modeled percent absorption values and the estimated levels previously reported in CAP 3C0107 (0.18 ml of hair dye reaching the scalp), considering an application of 6 ml of hair dye containing the maximum permitted 0.6 percent lead to the surface area of the full human scalp (580 cm²)—rather than only the 10 cm² area on the

forehead—for 24 hours. Assuming that the hair dye would be applied two times per week, FDA estimated that the daily exposure to lead would be significantly higher than what was previously thought in 1980 (see details in Ref. 3).

D. Petitioners' Assertion No. 4

“Overall exposure to lead in the United States has dropped since 1980 so FDA’s conclusion that the exposure was insignificant is no longer valid.” The petitioners argue that, since 1980, “both exposures and blood lead levels have dropped dramatically as a result of Congressional action to limit lead in consumer products and reduce exposure to the legacy of lead uses.” The petitioners provide information to demonstrate that the average blood lead level of an adult in the United States has decreased dramatically since 1980.

FDA Assessment: In the 1980 final rule on lead acetate, FDA stated that the average U.S. adult steady-state blood lead level was approximately 17 µg/dL. This amount was retained from the initial 35 µg of lead that was absorbed and internalized per day following normal human daily lead intakes of 100 to 500 µg from all food and environmental sources (45 FR 72112 at 72113). Based on the National Health and Nutrition Examination Survey (NHANES) results for 2015–2016, the geometric mean and 50th percentile (median) blood lead levels for U.S. adults 20 years and older were reported to be 0.920 µg/dL (95 percent confidence interval of 0.862–0.982 µg/dL) and 0.880 µg/dL (95 percent confidence interval of 0.810–0.960 µg/dL), respectively (Ref. 10). Therefore, we agree with the petitioners that the average adult blood lead level in the United States has decreased significantly since 1980 and our conclusion in 1980 that exposure to lead from the listed use of lead acetate hair dye is insignificant is no longer valid.

E. Petitioners' Assertion No. 5

“Post-1980 evidence indicates that lead acetate is likely to be ingested from typical use.” The petitioners provide publications by Mielke et al. (1997) (Ref. 11) and Deeb et al. (2014) (Ref. 12) to support their assertion that lead acetate in hair dye is likely to be ingested from typical use of lead acetate-containing hair dye, by both users of the dye and non-users (including children), from hand-to-mouth activity after contacting objects such as a faucet and comb contaminated with the hair dye or from touching a user’s hair.

FDA Assessment: The study by Mielke et al. measured the lead content of hair dyes and lead residues on hands

and on other surfaces, including combs, hair dye containers, hair drier handles, faucets, and telephone receivers, by users after applying lead acetate hair dye to their hair. Mielke et al. reported a wide range of residual lead levels on hands and surfaces touched by the hair dye user. FDA notes that the study results show a potential for lead from the lead acetate-containing hair dye product to transfer to other surfaces from the hands that have been in contact with the lead acetate-containing hair dye. However, the study by Mielke et al. did not evaluate ingestion of lead from these contaminated surfaces. Therefore, this study does not demonstrate that lead acetate is likely to be ingested from its use in hair dye. Deeb et al. reported on a case of a 52-year old male patient who presented with adverse effects attributed to repeated application of lead acetate-containing hair dye on his beard. We note that this is a report on one person that applied the hair dye to facial hair contrary to the required cautionary statement on the product. The color additive lead acetate is not approved for use in coloring facial hair and this would be considered a misuse of the product.

Therefore, FDA concludes that the information provided by the petitioners is not sufficient to support their assertion that ingestion is likely to occur from the approved use of lead acetate in hair dye (Ref. 2). Furthermore, FDA has not identified any other relevant scientific publications that demonstrate ingestion resulting from the regulated use of lead acetate in cosmetics intended for coloring hair on the scalp.

F. Petitioners' Assertion No. 6.

“Canada and Europe found the use of lead acetate as a color additive to be unsafe.” The petitioners make this assertion based on the decision of Health Canada and the European Union (EU) Scientific Committee on Cosmetic Products and Non-Food Products (SCCNFP) to prohibit the use of lead acetate in cosmetic products sold in Canada and the EU, respectively.

FDA Assessment: FDA has made its own determination on this petition based on our authority under the FD&C Act, independent of the actions taken by Canada and Europe regarding the use of lead acetate in hair dyes. However, we acknowledge that in 2004, the EU’s SCCNFP evaluated and issued an opinion on the use of lead acetate as a cosmetic ingredient, concluding that lead acetate is classified as “toxic to reproduction,” “may cause harm to the unborn child,” and that lead acetate should not be intentionally added to

cosmetic products marketed in the EU. Based on this opinion, the EU prohibited the use of lead acetate in cosmetic products in 2004 (Ref. 13).

FDA also acknowledges that Health Canada found that lead exposure resulting from regular use of lead acetate hair dyes when combined with other sources of lead exposure would result in an increasing cumulative exposure for lead that would potentially have adverse effects, particularly in sensitive populations. In 2005, based on data indicating skin absorption and possible links to carcinogenicity and reproductive toxicity, Health Canada prohibited the use of lead acetate in cosmetic products. Lead acetate-containing hair dyes have not been sold in the Canadian market since 2008 (Ref. 2).

VI. Updated Evaluation of Safety

During FDA's review of the petition, we evaluated the information provided by the petitioners and other information that has become available since 1980 when we listed lead acetate for use in hair dye to determine if there is still a reasonable certainty of no harm from the use of this color additive. FDA's basis for listing lead acetate in 1980, as previously stated, was that the absorbed amount of lead from hair dye containing lead acetate was "miniscule" when compared to the average person's background blood lead level and that the resulting increase in exposure from lead acetate-containing hair dye would have no discernible effect on the steady-state blood lead level. Our most recent review of the published literature (Ref. 2), combined with the flaws identified in the Moore study (see section V.B.), suggest that exposure to lead from the use of lead acetate-containing hair dyes is likely to be higher than was estimated in 1980. Considering all the information currently available, the data do not support the safe use of lead acetate as a color additive in cosmetics intended for coloring hair on the scalp.

In the 1980 final rule on lead acetate, FDA stated that the average person had a steady-state blood lead level of approximately 17 µg/dL (45 FR 72112 at 72113). This amount was retained from the initial 35 µg of lead that was absorbed and internalized per day following normal human lead intakes of 100 to 500 µg from all food and environmental sources. As discussed previously, the median blood lead level for U.S. adults 20 years and older based on 2015–2016 NHANES survey data was 0.88 µg/dL (Ref. 10). The NHANES data on blood lead levels indicates that lead exposure has decreased significantly in the U.S. general population. As a result,

any increase in exposure to lead resulting from use of lead acetate-containing hair dye can no longer be considered insignificant in terms of public health.

Considering: (1) The lack of evidence of a safe level of exposure for lead; (2) the reported adverse effects associated with low levels of lead exposure reported by NTP (discussed in section V.A.); (3) the statements and current recommendations by CDC and JECFA on lead exposure (discussed in section V.A.); (4) the deficiencies of the percutaneous absorption study by Moore et al. that may have resulted in an underestimate of exposure to lead from the use of lead-acetate containing hair dye (discussed in section V.B.); and (5) the significant reduction in median blood lead levels since 1980 (discussed in section V.D.), FDA concludes that the original basis for listing lead acetate is no longer valid and that there is no longer a reasonable certainty that no harm would result from the use of lead acetate as a color additive in cosmetics intended to color hair on the scalp.

VII. Applicability of the Delaney Clause

The Delaney Clause consists of two parts. The first part (section 721(b)(5)(B)(i) of the FD&C Act) pertains specifically to ingested color additives. The second part (section 721(b)(5)(B)(ii) of the FD&C Act) pertains to non-ingested color additives. In the 1980 final rule, FDA explained that because the first part of the Delaney Clause (section 721(b)(5)(B)(i) of the FD&C Act) is limited to uses that will or may result in ingestion, it does not apply to the use of lead acetate in hair dye used on the scalp (45 FR 72112 at 72115). In the final rule, FDA also determined, after evaluating scientific evidence relevant to the carcinogenic effects in experimental animals from feeding studies, that these studies are neither "appropriate" nor "relevant" to lead acetate used in hair dye, and therefore there was no basis to find the use of lead acetate in hair dye used on the scalp to be unsafe pursuant to the second part of the Delaney Clause (section 721(b)(5)(B)(ii) of the FD&C Act).

The petitioners argue that the 2004 NTP report designating lead and lead compounds (including lead acetate) as "reasonably anticipated to be human carcinogens based on limited evidence of carcinogenicity from studies in humans and sufficient evidence of carcinogenicity from studies in experimental animals," other published in vitro studies, and occupational exposure studies submitted in the petition are sufficient to make the conclusion that lead acetate is unsafe

and that section 721(b)(5)(B) of the FD&C Act should apply (Ref. 2). The petitioners argue that the first part of the Delaney Clause should apply based on their assertion that lead acetate in hair dye is likely to be ingested from typical use of lead acetate-containing hair dye for both users of the dye and non-users (including children), from hand-to-mouth activity after contacting objects such as a faucet contaminated with the hair dye or a user's hair with the dye—in other words, that there is incidental ingestion resulting from the intended use of the lead acetate in hair dye. To support this assertion, the petitioners submit publications by Mielke et al. and Deeb et al. (discussed in section V.E.). FDA concluded that the petition does not provide sufficient scientific evidence to support the petitioners' assertion of incidental ingestion resulting from typical use of lead acetate-containing hair dye. Because FDA has determined that the petition does not provide sufficient scientific evidence to support the assertions of ingestion from the use of lead acetate-containing hair dye, FDA has not found it necessary as part of its petition response to determine whether the first part of the Delaney Clause would apply to incidental ingestion of lead acetate from its use in hair dye.

The petitioner did not submit any information demonstrating carcinogenicity via dermal exposure, and FDA is not aware of any such information; FDA continues to find that the available animal feeding studies are not applicable or relevant to dermally applied lead acetate hair dyes under section 721(b)(5)(B)(ii) of the FD&C Act.

VIII. Comments on the Notice of Petition

We provided 60 days for comments on the notice of petition. A total of 220 individual comments were submitted to the docket after the notice of petition published. One group submitted a comment on behalf of 61 organizations, and another group submitted a comment supported by 26,198 signatures that they collected that were all in support of the petition. Overall, most of the comments did not contain any substantive new data or information that could inform FDA's evaluation of the petition. The overwhelming majority of the individual comments expressed support for granting the petition based on reported adverse health effects of lead and urged FDA to repeal the regulation.

(Comment 1) One comment, submitted by Combe, Inc. (Combe) urged FDA to deny the petition. Combe states that, in the 1970s, it marketed a cream-based hair dye product

containing 0.6 percent lead acetate trihydrate (0.34 percent lead) and a liquid formula containing 0.4 percent lead acetate trihydrate (0.23 percent lead). In 1998, Combe reformulated its liquid and foam lead acetate hair dye products to reduce the lead content. Combe states that the reformulated liquid product contains 0.28 percent lead acetate trihydrate (0.153 percent lead) and the foam product contains 0.25 percent lead acetate trihydrate (0.138 percent lead), thereby reducing the amount of lead absorbed daily to a level lower than the amount FDA considered to be safe in 1980. In its comment, Combe provides exposure estimates based on these reformulation levels.

Combe funded the 1978 radioactive tracer skin lead absorption study that was required by FDA (published by Moore et al. in 1980 (Ref. 1)), and emphasized that this study remains the only human skin lead absorption study using a hair dye formulation. Combe maintains that the amount of lead resulting from the use of its lead acetate hair dyes is trivial and considers the exposure to be essentially zero. Combe considers the studies submitted by the petitioners to be either inadequate or not pertinent to evaluating the safety of lead acetate under the intended conditions of use of the hair dye.

(Response) FDA agrees with Combe that some of the studies submitted in the petition had deficiencies in their designs, and the study results were inconsistent and difficult to interpret. FDA also agrees with Combe that the 1978 radioactive tracer skin lead absorption study (published in 1980 by Moore et al. (Ref. 1)) is applicable for studying human skin lead absorption. However, as discussed in section V, FDA identified several significant deficiencies in the Moore et al. study. In particular, Moore et al. applied the formulation to an 8 to 10 cm² surface area on the forehead, which is not consistent with the intended conditions of use for the hair dye product, this may have resulted in lowering absorption and underestimating the exposure to lead.

We acknowledge that the reformulation of Combe's hair dye products likely reduces exposure to lead as compared to use at the maximum permitted level. However, the regulation allows for use up to 0.6 percent lead in hair dyes; therefore, FDA must evaluate the safety of this maximum permitted use level. FDA also notes that Combe's updated estimated exposures for the reformulated products still relied on the dermal absorption results from the 1978 study that applied the test substance to

a small surface area on the forehead. Based on newer information available, application of formulations containing lead acetate to small skin surface area significantly limits the percentage of absorption, likely resulting in underestimating the exposure.

(Comment 2) Combe discusses the petitioners' reliance on the regulatory decisions by the EU and Canada to ban lead acetate. Combe refers to these decisions as grounded in the "precautionary principle," and states that the decisions were nonscientific resolutions of controversial issues that resulted in regulatory actions. Combe argues that such an approach is not permitted under the risk-based science standards required by the FD&C Act.

(Response) FDA is not relying on the decisions made by regulatory bodies of other governments in this action. Rather, FDA's determination is based on whether the available scientific evidence shows that there is a reasonable certainty of no harm from the use of this color additive.

(Comment 3) Combe states that since the 1960 Color Additive Amendments, FDA has issued several color additive (and food additive) regulations and that many of these regulations include specification limits for lead content that FDA considers to be "safe." Combe urges that, in its administrative and enforcement actions, FDA must be consistent in implementing the FD&C Act with respect to similar matters. Combe also asserts that the 10 parts per million (ppm) maximum lead level that FDA recommended for lead as an impurity in cosmetic lip products and externally applied cosmetics products in the draft guidance document entitled "Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level Guidance for Industry" is an "approval" and means that the exposure from its reformulated products should be considered safe. Specifically, Combe asserts that the "0.24 µg per day lead exposure that FDA determined is safe for adults from lipstick is 5 times more than the 0.046 µg per day lead exposure for adults from lead acetate in the current post-1998 Grecian Formula product."

(Response) FDA acknowledges that, since 1960, we have issued several color additive and food additive regulations that include maximum specification limits for lead (and other contaminants) that manufacturers are unable to avoid through good manufacturing practices and might be present as an impurity in the finished additives. However, we note that, unlike hair dyes, in which lead acetate is intentionally added as an

ingredient to achieve a coloring effect, these specification limits are for lead that may be present as an impurity in an approved additive. We also note that the specification limits for lead impurities in the finished additives are significantly lower than the 0.6 percent lead level (equivalent to 6,000 ppm) approved in § 73.2936 for use in hair dye products and the levels in Combe's reformulated hair dye products of 0.153 percent lead (equivalent to 1,530 ppm lead) and 0.138 percent lead (equivalent to 1,380 ppm lead). Typically, the levels specified for lead impurities in finished color additives and food additives are 20 ppm or lower. Such impurities might result during the manufacture of the additive (e.g., from impurities in starting materials) or occur naturally and is not the additive itself. FDA generally sets such specifications because it can be difficult to completely eliminate the presence of impurities such as lead.

The FDA draft guidance that Combe refers to recommends 10 ppm as the maximum level for lead as an impurity (not as an ingredient) in cosmetic lip products and externally applied cosmetics that are marketed in the United States. The estimated exposure of 0.24 µg/d to lead from cosmetic lip products that Combe refers to was a maximum exposure estimated by FDA based on incidental ingestion of lipstick containing lead at 10 ppm. However, contrary to Combe's assertions, our draft guidance is not an approval of this use, nor is it a safety determination. FDA considers the recommended maximum lead level of 10 ppm to be an achievable impurity level, with good manufacturing practices, for a wide range of cosmetics products. Unlike hair dyes where lead acetate is intentionally added as an ingredient to achieve a coloring effect, this recommended maximum level is for lead that may be present as an impurity in certain cosmetics.

FDA disagrees that it is being inconsistent in implementing the FD&C Act if it repeals the regulation regarding the use of lead acetate in hair dye under our color additive authority, while also establishing specifications for lead as an impurity in certain additives and providing a recommended maximum level for lead as an impurity in certain cosmetics. These actions are consistent with FDA's authority for color additives, food additives, and cosmetics, as well as our public health goal of reducing consumer exposure to lead to the greatest extent that is technically feasible.

IX. Conclusion

Following a full evaluation of the data submitted in support of CAP 7C0309 and other pertinent data and information, FDA has concluded that the data currently available no longer demonstrate that there is a reasonable certainty of no harm from the use of lead acetate as a color additive in hair dyes authorized under § 73.2396. This conclusion is based on the recognition of the current consensus that there is no safe exposure level for lead, deficiencies identified from our re-evaluation of the 1980 skin absorption study by Moore et al. that may have resulted in an underestimate of exposure to lead from its use in hair dye, and the fact that blood lead levels in the United States have dropped significantly since 1980, so we no longer can conclude that exposure to lead from lead acetate-containing hair dye has no discernible effect on the steady-state blood lead level. Therefore, to protect the public health, we are amending 21 CFR part 73 as set forth in this document. Upon the effective date (see **DATES**), use of lead acetate as a color additive in cosmetics intended for coloring hair on the scalp is no longer authorized.

FDA is exercising enforcement discretion for a period of 12 months from the effective date of the final rule regarding marketed hair dye products that contain the color additive lead acetate to provide an opportunity for industry to deplete the current stock of hair dye products with lead acetate and reformulate products prior to enforcing the requirements of this final rule. Such products must comply with the requirements of § 73.2396, including the specifications, uses and restrictions, and labeling requirements. This period of enforcement discretion takes into consideration the fact that bismuth citrate, which is listed in 21 CFR 73.2110 for use in cosmetic hair dye products at a level up to 2.0 percent weight/volume, is already being used as an alternative for lead acetate in hair dye products marketed both in the United States and other countries.

X. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, we will delete from the documents any materials that are not available for public disclosure.

XI. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the April 4, 2017, **Federal Register** notice of petition for CAP 7C0309. We stated that we had determined, under 21 CFR 25.32(m), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information that would affect our previous determination.

XII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XIII. Objections

This rule is effective as shown in the “DATES” section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>. We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

XIV. References

The following references marked with an asterisk (*) are on display at the

Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Moore, M.R., P.A. Meredith, W.S. Watson, et al., “The Percutaneous Absorption of Lead-203 in Humans From Cosmetic Preparations Containing Lead Acetate, as Assessed by Whole-Body Counting and Other Techniques,” *Food and Cosmetics Toxicology*, 18:399–405, 1980.
- *2. Memorandum from M. K. Wyatt, Cosmetics Division, OCAC, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, September 18, 2018.
- *3. Memorandum from H. Lee, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, September 19, 2018.
- *4. Center for Disease Control and Prevention, “What Do Parents Need to Know to Protect Their Children?” https://www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm.
- *5. Agency for Toxic Substances and Disease Registry (ATSDR), “Toxicological Profile for Lead,” August 2007. <https://www.atsdr.cdc.gov/toxprofiles/TP.asp?id=96&tid=22>.
- *6. U.S. Department of Health and Human Services, National Toxicology Program, “NTP Monograph on Health Effects of Low-Level Lead,” https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monograph/healtheffects/lowlevellead_newissn_508.pdf.
7. “Evaluation of Certain Food Additives and Contaminants: Seventy-Third Report of the Joint FAO/WHO Expert Committee on Food Additives,” WHO Tech Report Series No. 960. 2011. http://apps.who.int/iris/bitstream/10665/44515/1/WHO_TRS_960_eng.pdf.
- *8. U.S. Environmental Protection Agency, “Basic Information about Lead in Drinking Water. Health Effects of Exposures to Lead in Drinking Water. Is there a Safe Level of Lead in Drinking Water?” <https://www.epa.gov/ground-water-and-drinking-water/basic-information-about-lead-drinking-water>.
9. Delmaar, J.E., M.V. Park, and J.G. van Engelen, “ConsExpo—Consumer Exposure and Uptake Models,” RIVM report no. 320104004, <http://www.rivm.nl/en/Topics/C/ConsExpo>.
- *10. U.S. Department of Health and Human Services, Centers for Disease Control and

Prevention, "Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables, March 2018, Volume One." https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume1_Mar2018.pdf.

11. Mielke, H.W., M.D. Taylor, C.R. Gonzales, et al., "Lead-Based Hair Coloring Products: Too Hazardous for Household Use," *Journal of the American Pharmaceutical Association*, NS37:85–89, 1997b.
12. Deeb, W., D. Cachia, C. Quinn, et al., "Peripheral Neuropathy After Hair Dye Exposure: A Case Report," *Journal of Clinical Neuromuscular Disease*, 15:161–163, 2014.
- *13. The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers. Opinion Concerning Lead Acetate, SCCNFP/0832/04, July 1, 2004. http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out286_en.pdf.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

- 1. The authority citation for part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 73.2396 [Removed]

- 2. Remove § 73.2396.

Dated: October 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23725 Filed 10–30–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy (DoN), DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG) (Admiralty and Maritime Law) has determined that USS CINCINNATI (LCS 20) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective October 31, 2018 and is applicable beginning October 19, 2018.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Commander Kyle Fralick, JAGC, U.S. Navy, Admiralty Attorney, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave. SE, Suite 3000, Washington Navy Yard, DC 20374–5066, telephone number: 202–685–5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS CINCINNATI (LCS 20) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I, paragraph 2(a)(i), pertaining to the height of the forward masthead light above the hull; Annex I, paragraph 3(a), pertaining to the location of the forward masthead light in the forward quarter of the ship and the horizontal distance between the forward and after masthead light; Rule 21(a) and Annex I, paragraph 2(f)(i), requiring the masthead lights be above and clear of all other lights and obstructions; Annex I, paragraph 2(f)(ii) and Annex I, paragraph 3(c), pertaining to the horizontal and vertical spacing of task lights; and Rule 27(b)(i) and Annex I, paragraph 9(b), pertaining to the

visibility of task lights. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water).

For the reasons set forth in the preamble, the DoN amends part 706 of title 32 of the Code of Federal Regulations as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

- 1. The authority citation for part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

- 2. Section 706.2 is amended by:

- a. In Table One, adding, in alpha numerical order, by vessel number, an entry for USS CINCINNATI (LCS 20);
- b. In Table Four, under Paragraph 15, adding, in alpha numerical order, by vessel number, an entry for USS CINCINNATI (LCS 20);
- c. In Table Four, under Paragraph 16, adding, in alpha numerical order, by vessel number, an entry for USS CINCINNATI (LCS 20);
- d. In Table Four, under Paragraph 27, adding, in alpha numerical order, by vessel number, an entry for USS CINCINNATI (LCS 20); and
- e. In Table Five, adding, in alpha numerical order, by vessel number, an entry for USS CINCINNATI (LCS 20).

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *