4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

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

Reinstatement of Color Additive Listing for Lead Acetate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is reinstating the provision removed by our October 2018 final rule to amend the color additive regulations to no longer provide for the use of lead acetate in cosmetics intended for coloring hair on the scalp. This action does not reflect any change in our determination that new data demonstrate that there is no longer a reasonable certainty of no harm from the use of this color additive. We are reinstating this provision only because it was removed from the Code of Federal Regulations before we had the opportunity to take final action on the objections we received to the October 2018 final rule. This provision is being reinstated pending final FDA action on objections to the final rule.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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. Background

In the *Federal Register* of October 31, 2018 (83 FR 54665), FDA issued a final rule repealing the color additive regulation at § 73.2396 (21 Code of Federal Regulations (CFR) 73.2396) 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. We gave interested persons until November 30, 2018, to file objections and requests for a hearing on the final rule. The preamble to the final rule stated the effective date of the final rule would be on December 3, 2018, except as to any provisions that may be stayed by the proper filing of objections (83 FR 54665 at 54673). We received objections and a request for a hearing on the objections from a manufacturer of hair dyes containing lead acetate. Under sections 701(e)(2) and 721(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(e)(2) and 379e(d)), the filing of the objections operates to stay the effective date of the final rule until FDA takes final action on the objections. For access to the docket to read the objections 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.

Our October 2018 final rule provided an effective date of December 3, 2018, and, on that date, § 73.2396 was removed from the CFR. However, under the FD&C Act, the filing of the objections operates to stay the effectiveness of our revocation until we take final action on the objections. To implement a stay of effectiveness as required by sections 701(e)(2) and 721(d) of the FD&C Act, we need to restore § 73.2396 to the CFR. Thus, we are issuing this final rule to

reinstate § 73.2396 so that we may follow the appropriate process to address the objections that were filed. That provision will remain in place pending final FDA action on the objections to the October 2018 final rule. This action does not reflect any change in our determination that new data demonstrate that there is no longer a reasonable certainty of no harm from the use of this color additive.

FDA finds good cause for issuing this final rule without notice and comment under the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) and FDA regulations (§ 10.40(e)(1) (21 CFR 10.40(e)(1))). Notice and comment are unnecessary because this final rule is to correct the removal of a CFR provision where FDA's October 2018 final rule removing this provision was stayed under the FD&C Act pending final FDA action on objections to that rule. Therefore, we have determined that notice and comment is unnecessary. In addition, we find good cause for this final rule to become effective on the date of publication under 5 U.S.C. 553(d)(3) and § 10.40(c)(4)(ii).

II. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

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

IV. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the

Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Because the final rule does not impose compliance costs on small entities, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

V. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial

direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

VI. Consultation and Coordination with Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

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.

2. Add § 73.2396 to subpart C to read as follows:

§ 73.2396 Lead acetate.

(a) *Identity*. The color additive lead acetate is the trihydrate of lead (2 +) salt of acetic acid. The color additive has the chemical formula $Pb(OOCCH_3)_2 \cdot 3H_2O$.

(b) *Specifications*. Lead acetate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

(1) Water-insoluble matter, not more than 0.02 percent.

(2) pH (30 percent solution weight to volume at 25 °C), not less than 4.7 and not more than 5.8.

(3) Arsenic (as As), not more than 3 parts per million.

(4) Lead acetate, not less than 99 percent.

(5) Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions*. The color additive lead acetate may be safely used in cosmetics intended for coloring hair on the scalp only, subject to the following restrictions:

(1) The amount of the lead acetate in the cosmetic shall be such that the lead content, calculated as Pb, shall not be in excess of 0.6 percent (weight to volume).

(2) The cosmetic is not to be used for coloring mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp.

(d) *Labeling requirements*. (1) The label of the color additive lead acetate shall conform to the requirements of § 70.25 of this chapter, and bear the following statement or equivalent:

Wash thoroughly if the product comes into contact with the skin.

(2) The label of the cosmetic containing the color additive lead acetate, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, shall bear the following cautionary statement, conspicuously displayed thereon:

CAUTION: Contains lead acetate. For external use only. Keep this product out of children's reach. Do not use on cut or abraded scalp. If skin irritation develops, discontinue use. Do not use to color mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp. Do not get in eyes. Follow instructions carefully and wash hands thoroughly after each use.

(e) *Exemption for certification*. Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: March 27, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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