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Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level Guidance for Industry

Draft Guidance

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1130.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

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Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level¹ Guidance for Industry

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance provides a recommended maximum level of 10 parts per million (ppm) for lead as an impurity in cosmetic lip products and externally applied cosmetics that are marketed in the United States. FDA (or “we”) has concluded that a recommended maximum level of 10 ppm for lead as an impurity in cosmetic lip products and externally applied cosmetics would not pose a health risk. We consider the recommended maximum lead level to be achievable with the use of good manufacturing practices and to be consistent with the 10 ppm maximum lead level for similar products recommended by other countries. For additional discussion of the scientific and legal background and rationale underlying this recommended level, see “Supporting Document for Recommended Maximum Lead Level in Cosmetic Lip Products and Externally Applied Cosmetics” (<http://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm517327.htm>).

The issuance of this guidance supports our effort to limit human exposure to lead in finished FDA-regulated cosmetic products by educating new manufacturers who wish to enter the market and encouraging current manufacturers to continue to follow or improve on voluntary good manufacturing practices that limit trace amounts of lead as an impurity. This guidance applies to cosmetic lip products (such as lipsticks, lip glosses, and lip liners) and externally applied cosmetics (such as eye shadows, blushes, shampoos, and body lotions) marketed in the United States.² This guidance does not apply to topically applied products that are classified as drugs or to hair dyes that contain lead acetate as an ingredient.

¹ This guidance has been prepared by the Office of Cosmetics and Colors in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

² Cosmetic lip products are applied to the mucous membrane and therefore are not considered externally applied cosmetics (See 21 CFR 70.3(v)).

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FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

We regulate cosmetics under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and Fair Packaging and Labeling Act (FPLA). These laws require that cosmetics marketed in the United States be safe under their intended and customary conditions of use, and be properly labeled. Cosmetics are not subject to pre-market approval by FDA. However, pre-market approval is required for the color additives used as ingredients in cosmetics.

Although we have not set limits for lead as an impurity in cosmetics, most listed color additives have specifications for lead as an impurity as part of our requirements for their safe use. This guidance supports our effort to limit human exposure to lead in finished products by recommending a maximum level of 10 ppm lead as an impurity in cosmetic lip products and externally applied cosmetics.

The International Cooperation on Cosmetics Regulation and regions such as Canada and the European Union have set a limit of 10 ppm for lead as an impurity in cosmetics based on considerations of a reasonably achievable level, scientific risk assessment, good manufacturing practices, technical feasibility, and appropriate analytical methods (Refs. 1, 2). This guidance is consistent with those efforts.

III. Discussion

A. Recommended Maximum Lead Level in Cosmetic Lip Products and Externally Applied Cosmetics

Between 2007 and 2009, FDA scientists developed and validated a total dissolution method for analyzing lead in lipstick and used this method to determine the lead content in a selection of 20 commercially available lipsticks on the U.S. market (Ref. 3). In 2010, using the same analytical method, we obtained results for lead content in 400 lipsticks and other cosmetic lip products available in the U.S., and in 2012, obtained similar results for an additional 30 cosmetic lip products (Refs. 4, 5, 6, 7). Finally, between 2012 and 2013, we used a more common extraction method for determining lead in an additional 29 cosmetic lip products (Ref. 7). The lead levels found in our surveys ranged from 0.026 ppm (the detection limit of the total dissolution method for the studies) to a maximum of 7.19 ppm in one lipstick. The average lead concentration was 1.09 ppm.

Between 2011 and 2012, we used a total dissolution method to obtain results for lead content in 120 externally applied cosmetic products available on the U.S. market, which included eye shadows, blushes, body lotions, mascaras, foundations, body powders, compact powders,

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shaving creams, and face paints (Refs. 6, 7). Between 2012 and 2013, we used the extraction method for determining lead in an additional 86 externally applied cosmetics (Ref. 7). The lead levels found in our surveys ranged from 0.0084 ppm (the detection limit of the total dissolution method for these studies) to a maximum of 14 ppm in one eye shadow and one blush. The average lead concentration ranged from below the detection limit in shaving creams to 4.6 ppm in compact powders.

These surveys indicate that levels of lead in the cosmetic lip products and externally applied cosmetics we have sampled are for the most part well below 10 ppm, leading us to expect that this recommended maximum level is achievable by all manufacturers of these products. However, in our surveys, which do not necessarily reflect the full range of products that are currently on the market, a small number of samples had lead levels that exceed the maximum level we are recommending. Our goal is to ensure that cosmetic lip products and externally applied cosmetics do not contain lead as an impurity at levels that would pose a health risk. We have determined that a maximum level of 10 ppm in cosmetic lip products and externally applied cosmetics would not pose a health risk, but we encourage manufacturers of these products to follow or continue to follow manufacturing practices that allow them to achieve levels of lead lower than 10 ppm whenever feasible.

We have concluded that a maximum level of 10 ppm for lead as an impurity in cosmetic lip products and externally applied cosmetics should be readily achievable by manufacturers that source their ingredients appropriately and use good manufacturing practices. Modern analytical capability permits determination of lead at ppm levels, thus enabling manufacturers to avoid the purchase of ingredients with unacceptably high levels of lead and to determine whether lead is introduced into their products during the manufacturing process.

B. Exposure Assessment and Public Health Impact of Recommended Maximum Lead Level in Cosmetic Lip Products and Externally Applied Cosmetics

As explained in more detail in our supporting document, the routes of exposure to lead from cosmetic lip products are incidental ingestion and dermal absorption and the route of exposure to lead from externally applied cosmetics is dermal absorption. To assess the exposure to lead from cosmetic lip products and externally applied cosmetic products, we assumed these products contain 10 ppm lead because, as noted above, that impurity level should be readily achievable by manufacturers. Additionally, 10 ppm lead is consistent with the 10 ppm maximum lead level for similar products recommended by the International Cooperation on Cosmetics Regulation and regions such as Canada and the European Union.

1. Exposure to Lead from Cosmetic Lip Products

The composition of cosmetic lip products limits the ability for lead present as an impurity to diffuse from a product and be absorbed by the skin. Therefore, dermal absorption of lead from cosmetic lip products is negligible, and we have concluded that systemic exposure to lead from these products is primarily by incidental ingestion.

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We used an approach previously employed by FDA for estimating exposure to lead from food to estimate exposure to lead from cosmetic lip products (Ref. 8). We estimated that maximum exposure to 10 ppm lead from a cosmetic lip product is 0.24 $\mu\text{g}/\text{day}$ for adults and adolescents age 13 years or older and 0.024 $\mu\text{g}/\text{day}$ for children age 12 years or younger (assuming that children age 12 years or younger use 10% as much of these products as adults) (Ref. 9). We determined that the potential elevation of blood lead levels from 10 ppm lead in these products is too small to be measured in routine blood analysis and requires state of the art analytical technology (Ref. 10).

2. Exposure to Lead from Externally Applied Cosmetics

Dermal absorption of lead from externally applied cosmetics is very small. Results for lead uptake by the skin were reported for four lead compounds that resemble cosmetic ingredients (Ref. 11). Based on those data, we estimated that only a very small amount (0.41%) of the lead present as an impurity in an externally applied cosmetic is absorbed by the skin.

The amount of exposure to lead as an impurity in externally applied cosmetics depends on whether the product is a “leave-on” product (such as eye shadow or body lotion) or a “rinse-off” product (such as shampoo or shaving cream). The amount of exposure also depends on how much product is applied to the skin. For example, eye shadows are applied in very small amounts (40 mg/day) and only around the eyes (Ref. 12). Because dermal absorption of lead is so small, we estimated that exposure to 10 ppm lead from an eye shadow is only 1.64×10^{-3} $\mu\text{g}/\text{day}$ for adults and adolescents age 13 years or older and 1.64×10^{-4} $\mu\text{g}/\text{day}$ for children age 12 years or younger (assuming that children age 12 years or younger use 10% as much eye shadow as adults). This means that exposure to lead from an eye shadow is approximately 150 times lower than exposure to lead from a cosmetic lip product.

The amount of exposure to lead as an impurity in a product such as body lotion is higher because average applications are higher (8.7 g/day) (Ref. 9). Based on body surface area calculations from reported height and weight data, we estimated that children age 6-18 use 65% as much body lotion as adults age ≥ 19 and children age 1-5 use 34% as much body lotion as adults age ≥ 19 (Refs. 10, 13). We then estimated that exposure to 10 ppm lead from a body lotion is 0.36 $\mu\text{g}/\text{day}$ for adults age ≥ 19 , 0.23 $\mu\text{g}/\text{day}$ for children age 6-18, and 0.12 $\mu\text{g}/\text{day}$ for children age 1-5. In addition, our surveys found that body lotions actually contain very little lead (0.04 to 0.10 $\mu\text{g}/\text{g}$) (Refs. 6, 7). Therefore, we estimated that exposure to lead from a body lotion containing 0.10 $\mu\text{g}/\text{g}$ (0.10 ppm) lead is 0.0036 $\mu\text{g}/\text{day}$ for adults age ≥ 19 , 0.0023 $\mu\text{g}/\text{day}$ for children age 6-18, and 0.0012 $\mu\text{g}/\text{day}$ for children age 1-5, or 67 times lower for adults and up to 20 times lower for children than exposure to lead from a cosmetic lip product.

Exposure to lead from externally applied cosmetics is up to 150 times lower than exposure to lead from cosmetic lip products. Therefore, the potential elevation of blood lead levels from 10 ppm lead in these products is too small to be measured in routine blood analysis and requires state of the art analytical technology (Ref. 10).

3. Public Health Impact of Recommended Maximum Lead Level in Cosmetic Lip Products and Externally Applied Cosmetics

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Based on our exposure assessment, we have concluded that a recommended maximum level of 10 ppm for lead as an impurity in cosmetic lip products and externally applied cosmetics would not pose a health risk. The issuance of this guidance supports our effort to limit human exposure to lead in finished FDA-regulated cosmetic products by educating new manufacturers who wish to enter the market and encouraging current manufacturers to continue to follow or improve on voluntary good manufacturing practices that limit trace amounts of lead as an impurity. We consider the recommended maximum lead level to be achievable with the use of good manufacturing practices and to be consistent with the 10 ppm maximum lead level for similar products recommended by other countries.

Lead is a chemical element for which toxicity in humans has been well documented (Ref. 14). It may occur as an impurity in any of the ingredients used in cosmetic lip products and externally applied cosmetics due to its background presence in the environment. Cosmetics manufacturers are responsible for avoiding potentially harmful levels of lead in their finished products. Our data show that over 99% of the cosmetic lip products and externally applied cosmetics on the U.S. market contain lead at levels below our recommended maximum level. Therefore, we encourage firms to continue the manufacturing practices that achieve these lower levels of lead in their finished products.

C. Enforcement Policy for Lead in Cosmetic Lip Products and Externally Applied Cosmetics

FDA is prepared to take enforcement action against any cosmetic lip product or externally applied cosmetic containing lead at levels that may harm consumers. FDA intends to consider several factors in bringing enforcement actions regarding lead in cosmetic lip products and externally applied cosmetics, including the level of lead present, the particular product, and the conditions of use for the product.

IV. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of December 20, 2016, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after December 20, 2016.

1. International Cooperation on Cosmetics Regulation, “Considerations on Acceptable Lead Levels in Cosmetic Products,” December 2013, available at <http://iccrnet.org/topics/>.
2. Health Canada, “Guidance on Heavy Metal Impurities in Cosmetics,” July 20, 2012, available at http://www.hc-sc.gc.ca/cps-spc/pubs/indust/heavy_metals-metaux_lourds/index-eng.php.
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5. U.S. Food and Drug Administration, “Limiting Lead in Lipstick and Other Cosmetics,” December 2016, available at <http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm137224.htm>.

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8. Carrington, C. D., and Bolger, P. M., “An assessment of the hazards of lead in food,” *Regulatory Toxicology and Pharmacology*, vol. 16, pp. 265-272, 1992.

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10. Centers for Disease Control and Prevention, “National Health and Nutrition Examination Survey,” available at <http://www.cdc.gov/nchs/nhanes.htm>.

11. Bress, W. C., and Bidanset, J. H., “Percutaneous in vivo and in vitro absorption of lead,” *Veterinary and Human Toxicology*, vol. 33, pp. 212-214, 1991.

12. Loretz, L. J., Api, A. M. Api, Babcock, L., Barraj, L. M., Burdick, J., Cater, K. C., Jarrett, G., Mann, S., Pan, Y. H. L., Re, T. A., Renskers, K. J., and Scrafford, C. G., “Exposure data for cosmetic products: Facial cleanser, hair conditioner, and eye shadow,” *Food and Chemical Toxicology*, vol. 46, pp. 1516–1524, 2008.

13. El Edelbi, R., Lindemalm, S., and Eksborg, S., “Estimation of body surface area in various childhood ages – validation of the Mosteller formula,” *Acta Pædiatrica*, vol. 101, pp. 540-544, 2012.

14. Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry, “Toxicological Profile for Lead,” available at <http://www.atsdr.cdc.gov/ToxProfiles/tp13.pdf>.