Supporting Document for Recommended Maximum Lead Level in Cosmetic Lip Products and Externally Applied Cosmetics

December 2016

[Docket No. FDA-2014-D-2275]

Table of Contents

I. Introduction

The purpose of this document is to present the scientific and legal background and rationale for the Food and Drug Administration's (FDA's) recommended maximum level of 10 parts per million (ppm) for lead as an impurity in cosmetic lip products and externally applied cosmetics, described in "Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level – Guidance for Industry." 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.

The issuance of the guidance document 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. The 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. The guidance does not apply to topically applied products that are classified as drugs or to hair dyes that contain lead acetate as an ingredient.

Lead is a chemical element for which toxicity in humans has been well documented (Ref. 1). 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. Low levels of lead can be achieved through reasonable and practical approaches to control raw materials, and through other good manufacturing practices. We have published good manufacturing practice recommendations for cosmetics manufacturers that can be used in conjunction with appropriate sourcing to avoid lead levels in cosmetic lip products and externally applied cosmetics that would potentially harm consumers (Ref. 2).

The guidance document supports FDA's effort to limit human exposure to lead by recommending a maximum level of 10 ppm for lead as an impurity in cosmetic lip products and externally applied cosmetics. Data supporting our guidance have been obtained, in part, from our surveys of approximately 685 cosmetic products sold on the U.S. market between 2009 and 2012.

II. FDA Regulation of Cosmetics

FDA regulates cosmetics under sections 201(i) and 601-603 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §§ 321(i) and 361-363) and the Fair Packaging and Labeling Act (FPLA) (15 U.S.C. § 1451 et seq.). These laws require that cosmetics marketed in the United States be safe under their intended or customary conditions of use, and be properly labeled. The manufacturer or distributor has the responsibility to ensure that cosmetics are safe and in compliance with the FD&C Act and the FPLA. FDA may take regulatory action if a cosmetic is adulterated or misbranded.

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.

III. Composition of Cosmetic Lip Products and Externally Applied Cosmetics

The most common cosmetic lip product is lipstick, which is a mixture of waxes, oils, and coloring agents (Ref. 3). Other cosmetic lip products such as lip glosses and lip liners have similar formulations (Ref. 4). The intended use of all of these cosmetic products is similar and the products differ only in the specific area and manner of application to the lips.

Waxes and oils typically account for more than half the total weight of cosmetic lip products. Polymers combined with volatile oils such as cyclomethicone make the products last longer on the lips. Other ingredients include alcohols, esters, fragrances, and preservatives.

Examples of externally applied cosmetics include bath products, blushes, body powders, compact powders, deodorants, eye shadows, face paints, foundations, hair products, lotions, mascaras, nail products, shaving preparations, skin care preparations, and tanning preparations. These products have various formulations depending on their intended uses (Refs. 3, 4). Polymers, alcohols, esters, fragrances, and preservatives are frequently used ingredients, as well as oils, glycerin, and water.

Coloring agents are important ingredients of cosmetic lip products, eye shadows, and other cosmetics that are intended to impart color to the skin. The ingredients include dyes, lakes and other pigments, inorganic oxides and salts, and minerals. Dyes are used to stain the lips and impart color to other parts of the face, while lakes and other pigments are used for their brightening and covering effects. Mica adds sparkle effects. Talc and clay minerals are used as pigment extenders and fillers. Products such as body lotions, shaving creams, and shampoos that are not intended for coloring the skin may contain small amounts of coloring agents.

Small amounts of lead are more likely to be found in unprocessed mineral compounds such as talc and clay than in other cosmetic ingredients. In addition, the color additives listed by FDA for use in coloring cosmetics are permitted to contain from 10 to 20 ppm[1] of lead as an impurity. The total amount of lead in a finished cosmetic product would be much less, however, because cosmetic products usually do not contain more than about 20% color additives.

IV. FDA's Initial Survey of Lead in Lipstick

In October 2007, the Campaign for Safe Cosmetics (CSC) reported analytical results for lead in 25 shades from 14 brands of lipstick (Ref. 5). Immediately after publication of CSC's report, FDA's Center for Food Safety and Applied Nutrition (CFSAN) began collecting commercial samples of the reported lipstick brands available on the U.S. market in order to independently assess possible lead contamination of lipstick products on the market.

From October to December 2007, CFSAN purchased samples of 20 shades of commercial lipsticks, marketed under 12 brands and manufactured by 9 firms. Multiple samples with the same lot number were obtained for several shades. Most of the lipsticks purchased by CFSAN had been analyzed for CSC's report.

FDA scientists developed and validated a total dissolution method for the determination of lead content in lipstick by microwave-assisted hydrofluoric acid/nitric acid digestion and inductively coupled plasma-mass spectrometry (ICP-MS) (Ref. 6). FDA scientists detected lead in all of the lipstick samples analyzed. The results for lead ranged from 0.09 ppm to 3.06 ppm. The detection

[1] The unit of milligrams per kilogram (mg/kg) is more accurate than the unit of parts per million (ppm) for solid compounds. However, both units are commonly used for reporting low levels of impurities. The equivalent unit of micrograms per gram (μg/g) is frequently used for reporting analytical results for lead in the scientific literature and is used in calculations reported in this document.

limit was estimated to be 0.04 ppm. The mean (average) concentration found in the lipsticks was 1.07 ppm.

FDA's results for lead from the survey of 20 lipsticks were all higher than the levels in CSC's report. We note that CSC's method for digesting the samples was not capable of dissolving the silicate minerals frequently used as lipstick pigments. In addition, the use of sulfuric acid for digesting the samples may have resulted in lower lead levels because some of the lead may have been converted to insoluble lead sulfate, unavailable for analysis by ICP-MS.

In 2009, we published the validated method and survey results, without identifying the specific lipsticks analyzed, in the peer-reviewed Journal of Cosmetic Science (Ref. 6). We also updated our website to include the lipstick identifications (Ref. 7).

V. FDA's Expanded Survey of Lead in Cosmetic Lip Products

In 2010, we conducted an expanded survey of lead content in a broad range of cosmetic lip products having a variety of shades, prices, and manufacturers. The purposes for the expanded survey were to ascertain the levels of lead in cosmetic lip products sold in the U.S. market, to compare the results to those from the initial survey, and to identify any categories of cosmetic lip products with elevated levels of lead.

We tested 400 cosmetic lip products available on the U.S. market for lead content using FDA's validated total dissolution method. The analyses were performed by Frontier Global Sciences, Inc., a private laboratory based in Seattle, WA.

We selected the cosmetic lip products by choosing manufacturers, brands, and shades that reflected the products currently on the market. This was accomplished by proportioning the number of cosmetic lip products chosen from each brand to its market share (Ref. 8), except that a few cosmetic lip products were selected from niche markets in an effort to capture cosmetic lip products with unusual characteristics. The results from the expanded survey ranged from the detection limit of 0.026 ppm to the highest value of 7.19 ppm. All but two cosmetic lip products we surveyed had lead levels below 5 ppm. The mean (average) lead concentration was 1.11 ppm, very close to the average of 1.07 ppm obtained in the initial survey. The standard deviation for the expanded survey was 0.97 ppm. We updated our website in 2011 to include these results, and we published our findings in 2012 in the Journal of Cosmetic Science (Refs. 7, 9).

Our expanded survey was intended to determine the lead content in lipsticks, rather than all cosmetic lip products, and our findings are attributed to lipsticks in our publications. However, based on the product names, the expanded survey actually included 394 lipsticks, one lip gloss, and five cosmetic lip balms. We did not consider including lip liners, such as lip pencils and encased ("automatic") lip liners in our survey, due to their additional sampling challenges. Nevertheless, based on their similar formulations and intended use, our data and conclusions for lipsticks apply equally to other cosmetic lip products such as lip glosses, cosmetic lip balms, and lip liners.

VI. Additional FDA Surveys of Lead in Cosmetic Lip Products

Between 2011 and 2012, FDA conducted a third survey of lead in 30 cosmetic lip products available on the U.S, market that included 29 lipsticks and one cosmetic lip balm. The survey, completed in March 2012, used our validated total dissolution method for analyzing lead. We chose products by market share and from niche markets as described above. FDA again contracted with Frontier Global Sciences, Inc. of Seattle, Washington to perform the analyses.

The results from the third survey ranged from the detection limit of 0.0084 ppm to the highest value of 3.4 ppm. The mean (average) lead concentration was 1.0 ppm, very close to the averages of the two previous surveys. We published our findings in the Journal of Cosmetic Science and on our website (Refs. 10, 11).

Between 2012 and 2013, we conducted a fourth survey that used an extraction method for determining lead in 29 cosmetic lip products available on the U.S. market that included 27 lipsticks and two cosmetic lip balms. We contracted with Environmental Monitoring and Technologies, Inc. of Morton Grove, Illinois for this survey. The contractor used nitric acid for extracting lead from samples and inductively coupled plasma-optical emission spectrometry (ICP-OES) for determining lead in the extracts. We chose this method because we wanted to obtain results with a common method that used a more easily handled substance for digesting the samples than our total dissolution method. All of the lead results were below the practical quantitation limit of the extraction method (Ref. 11).

VII. FDA's Surveys of Lead in Externally Applied Cosmetics

At the same time we conducted our third survey of cosmetic lip products, we also conducted a survey of 120 externally applied cosmetic products available on the U.S. market that included 30 eye shadows, 30 blushes, 15 face and body lotions (5 medium or low-priced, 5 premium or high-priced, and 5 with sunscreen), 10 mascaras, 10 foundations, 5 body powders, 5 compact powders, 5 shaving creams, and 10 face paints. Products were chosen by market share and niche markets as described above, with an emphasis on products we considered likely to contain high amounts of lead due to their high solid filler (such as clay or talc) and pigment content (i.e., eye shadows and blushes).

The results for lead in the externally applied cosmetic products were obtained by a total dissolution method and ranged from the detection limit of 0.0084 ppm to the highest value of 14 ppm lead for one eye shadow and one blush (Refs. 10, 11). The mean (average) lead concentrations were 4.2 ppm for eye shadows, 3.9 ppm for blushes, 0.010 ppm for medium and low-priced lotions, 0.019 ppm for high-priced lotions, 0.019 ppm for lotions with sunscreen, 0.13 ppm for mascaras, 0.64 ppm for foundations, 0.48 ppm for body powders, 4.6 ppm for compact powders, NF (none found) for shaving creams, and 1.0 ppm for face paints. The relatively high results for eye shadows, blushes, and compact powders were consistent with high solid filler and pigment content, suggesting that the contaminant may originate in the mineral components (Ref. 10).

We conducted a second survey of 204 externally applied cosmetics available on the U.S. market at the same time that we conducted the fourth survey of cosmetic lip products, again using the more common acid extraction method. More than half (118) of the externally applied cosmetics we tested in this survey had been tested in the previous survey, and the results were the same or less than the previous results. Most results for the 86 newly analyzed products were below the practical quantitation limit of the extraction method, except that lead levels ranging from 6.7 to 9.4 ppm were found in four eye shadows and 5.0 ppm lead was found in one blush (Ref. 11).

VIII. FDA's Recommended Maximum Lead Level in Cosmetic Lip Products and Externally Applied Cosmetics

Together, our surveys provided results for lead content in 685 cosmetic lip products and externally applied cosmetic products. The average value for lead in the cosmetic lip products was 1.0 ppm. Average values for lead in the externally applied cosmetics ranged from below the detection limit for shaving creams to 4.6 ppm for compact powders, with a maximum of 14 ppm for one eye shadow and one blush. All but four externally applied cosmetics we surveyed had lead levels below 10 ppm.

Our surveys of externally applied cosmetic products emphasized products we considered likely to contain high amounts of lead due to their high filler and pigment content (i.e., eye shadows, blushes, and compact powders), and we found that those products contained the highest levels of lead. Other products we surveyed such as body lotions and shaving creams contained very low levels of lead, as we expected from their formulations.

Based in part on the data from our surveys, we are recommending a maximum level of 10 ppm for lead as an impurity in 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. Our surveys have shown that manufacturers have the ability to limit lead content in these products to 10 ppm or below. The low levels of lead we found in most of the surveyed products indicate that the manufacturers of those products were likely to have sourced their ingredients appropriately and to have used good manufacturing practices during the production of their products. Additionally, as discussed below, based on exposure estimates, we conclude that a maximum level of 10 ppm for lead as an impurity in cosmetic lip products and externally applied cosmetics would not pose a health risk.

Our recommended maximum lead level in cosmetic lip products and externally applied cosmetics is consistent with the 10 ppm maximum level recommended by other public health authorities for lead as an impurity in cosmetic products. The International Cooperation on Cosmetic Regulation (ICCR, a voluntary group of cosmetics regulatory authorities consisting of the FDA; Ministry of Health, Labor, and Welfare of Japan; European Directorate General for Enterprise and Industry; and Health Canada) recommends a limit of 10 ppm for lead as an impurity in cosmetic products (Ref. 12). The ICCR recommendation is based on considerations of a reasonably achievable level, scientific risk assessment, good manufacturing practices, technical feasibility, and appropriate analytical methods. Health Canada considers a concentration of lead exceeding 10 ppm in cosmetic products to be "technically avoidable" (Ref. 13).

IX. Estimated Exposure to Lead from Cosmetic Lip Products

To estimate the exposure to lead from cosmetic lip products, as well as from externally applied cosmetic products as discussed below, we assumed these products contain a level of 10 ppm lead. We used 10 ppm lead in our calculations because, as noted above, that level should be readily achievable by manufacturers. Additionally, as noted above, 10 ppm lead is consistent with the recommended 10 ppm maximum level set by the International Cooperation on Cosmetics Regulation and regions such as Canada and the European Union.

The routes of exposure to lead from cosmetic lip products are incidental ingestion and dermal absorption and we have addressed both pathways. Cosmetic lip products consist primarily of waxes and oils and resemble petrolatum (petroleum jelly), which is a poor solvent for lead and other metal salts (Refs. 14, 15). The composition of cosmetic lip products is such that consumers (i.e., children) would be unable to eat an entire tube of lipstick because it would make a person ill. In addition, the composition of these 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 these products is negligible, and we have concluded that systemic exposure to lead from these products is primarily by incidental ingestion. Details of our analysis are presented elsewhere (Ref. 16), and we summarize our conclusions here.

Average usage of lipstick by U.S. women has been reported as 10 mg per application and 24 mg per day (Refs. 17, 18, 19). Cosmetic lip products all have similar formulations, and the intended use of these products is similar. Therefore, 24 mg per day is a realistic estimate of actual usage of cosmetic lip products in the U.S. This means that a typical 3 gram (0.11 ounce) tube of lipstick, for example, would be used up in about 4 months.

We used an approach previously employed by FDA for estimating exposure to lead from food to estimate exposure to 10 ppm lead from cosmetic lip products (Refs. 20, 21, 22, 23). Using lipstick as an example in our analysis, we estimated the impact of exposure to lead from cosmetic lip products on blood lead levels. In our analysis, we assumed the use of lipstick by children age 12 years or younger to be 10% of the use by adults. Our 10% estimate is a subjective estimate; children age 12 years or younger do not typically wear lipstick. We estimated that average exposure to lead from cosmetic lip products is 0.24 µg/day for adults and adolescents age 13 years or older and 0.024 µg/day for children age 12 years or younger.

We used data for average blood lead levels reported in 2011-2012 for adults age ≥19, females age 18-45, children age 6-17, and children age 1-5 to estimate the impact of exposure to 10 ppm lead from lipstick and other cosmetic lip products (Ref. 24). We estimated that blood lead levels resulting from this exposure range from 0.0012 µg/dL for children age 1-12 to 0.017 µg/dL for adults age ≥19, females age 18-45, and adolescents age 13 years or older. The maximum impact of 10 ppm lead from lipstick on the reported average blood lead levels is 1.17% for adults age

≥19, 2.13% for females age 18-45, 2.27% for adolescents age 13 years or older, 0.51% for children age 6-12, and 0.30% for children age 1-5.

Our calculations show that the impact of 10 ppm lead from cosmetic lip products on the blood lead levels of females age 18-45 and adolescents age 13 years or older is expected to be very similar, which is a realistic finding. Furthermore, the maximum impact of 10 ppm lead from cosmetic lip products on the blood lead levels of adults and adolescents age 13 years or older is only 1-2%. The potential elevation of blood lead levels by 10 ppm lead from cosmetic lip products is too small to be detected in typical routine blood analyses and requires the use of state of the art analytical technology (Refs. 25, 26).

X. Estimated Exposure to Lead from Externally Applied Cosmetics

The route of exposure to lead from externally applied cosmetics is dermal absorption. The amount of exposure 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) and how much product is applied to the skin. However, just as for cosmetic lip products, the composition of these products limits the ability for lead present as an impurity to diffuse from a product and be absorbed by the skin. Details of our analysis are presented elsewhere (Ref. 16), and we summarize our conclusions here.

Usage data have been reported for the following externally applied cosmetic products: body lotion, face cream, hair spray, spray perfume, liquid foundation, shampoo, body wash, facial cleanser, hair conditioner, and eye shadow (Refs. 17, 27, 28). Average (mean) usage of these products was found to range from 40 mg/day for eye shadow to 8.7 g/day for body lotion to 14.5 g/day for body wash. Of these product types, we have the most analytical data for eye shadow and body lotion (Ref. 10). Therefore, we used eye shadow and body lotion as representative leave-on products for estimating dermal exposure to 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. 29). 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 (Ref. 16).

In our analysis, we assumed the exposure to lead from eye shadows for children age 12 years or younger is 10% of that for adults and adolescents age 13 years and older. Our 10% estimate is a subjective estimate; children age 12 years or younger do not typically wear eye shadow. We estimated that average dermal exposure to lead from eye shadows containing 10 ppm lead (10 μg Pb/g) is 1.64×10^{-3} μg/day for adults and adolescents age 13 years or older and 1.64×10^{-4} μg/day for children age 12 years or younger. This means that exposure to lead from an eye shadow is approximately 150 times lower than exposure to lead from a cosmetic lip product.

We assumed the exposure to lead from body lotion for children age 6-18 is 65% of that for adults age ≥19 and for children age 1-5 is 34% of that for adults. Our assumptions about body lotion are based on height and body weight data reported in 2011-2012 for adults age ≥19, children age <19, and children age 1-5 and body surface area calculations based on those data (Refs. 16, 24, 30).

We estimated that average dermal exposure to lead from body lotion containing 10 ppm lead (10 µg Pb/g) is 0.36 µg Pb/day for adults age ≥19, 0.23 µg Pb/day for children age 6-18, and 0.12 µg Pb/day for children age 1-5. In addition, our surveys found that body lotions actually contain very little lead (0.04 to 0.10 µg/g) (Ref. 10). Therefore, we estimated actual exposure to lead from a body lotion containing 0.10 µg/g (0.10 ppm) lead to be 0.0036 µg/day for adults age ≥19, 0.0023 µg/day for children age 6-18, and 0.0012 µg Pb/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. 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 (Refs. 25-26).

XI. Summary and Conclusions

We are recommending a maximum level of 10 ppm for lead as an impurity in cosmetic lip products (such as lipsticks, lip glosses, and lip liners) and externally applied cosmetics (such as eye shadows, blushes, shampoos, and body lotions) that are marketed in the U.S. Data supporting our recommendation come, in part, from the four surveys we conducted of lead content in 685 cosmetic lip products and externally applied cosmetics on the U.S. market.

Our surveys have shown that cosmetics manufacturers have the ability to limit lead content in cosmetic lip products and externally applied cosmetics to 10 ppm or below. The low levels of lead we found in the surveyed products indicate that the manufacturers were likely to have sourced their ingredients appropriately and to have used good manufacturing practices in order to achieve low levels of lead in their finished products.

Exposure to lead present as an impurity in cosmetic lip products is from dermal absorption and incidental ingestion. 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. We used an approach previously employed by FDA for estimating exposure to lead from food to estimate exposure to lead from cosmetic lip products. We determined that the potential elevation of blood lead levels by 10 ppm lead from cosmetic lip products is too small to be detected in typical routine blood analyses and requires the use of state of the art analytical technology.

Exposure to lead present as an impurity in externally applied cosmetics is from dermal absorption, which is very small. Based on studies reported in the scientific literature, 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. Because dermal absorption of lead is so small, we estimated exposure to 10 ppm lead from an eye shadow to be only 1.64×10^{-3} µg /day for adults and adolescents age 13 years or older and 1.64×10^{-4} µg/day for children age 12 years or younger (assuming that children age 12 years or younger use 10% as much eye shadow as adults and adolescents age 13 years or older). 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). Nevertheless, because dermal absorption of lead is so small, exposure to 10 ppm lead from a body lotion is estimated to be only 0.36 µg/day for adults age ≥19, 0.23 µg/day for children age 6-18 and 0.12 µg/day for children age 1-5 (assuming that children age 6-18 use 65% as much body lotion as adults and children age 1-5 use 34% as much body lotion as adults, based on body surface areas). In addition, our surveys found that body lotions actually contain very little lead (0.04 to 0.10 µg/g). Therefore, we estimated exposure to lead from a body lotion containing 0.10 µg/g (0.10 ppm) lead to be 0.0036 µg/day for adults age ≥19, 0.0023 µg/day for children age 6-18, and 0.0012 µg/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.

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. A recommended maximum of 10 ppm for lead as an impurity in cosmetic lip products and externally applied cosmetics 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. 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.

Our 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.

A maximum level of 10 ppm 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 use of ingredients with unacceptably high levels of lead and to determine whether lead is introduced during the manufacturing process. These efforts will assure that manufacturers continue to achieve low levels of lead in their finished products.

XII. 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. 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 .

2. U.S. Food and Drug Administration, "Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist," available at http://www.fda.gov/cosmetics/guidanceregulation/guidancedocuments/ucm2005190.htm.

3. Korichi, R., and Tranchant, J.-F., "Decorative Products," *in* Handbook of Cosmetic Science and Technology, 3rd ed., A. O. Barel, M. Paye, and H. I. Maibach, eds., Informa Healthcare, New York, NY, 2009, pp. 391-397.

4. Food and Drug Administration, Voluntary Cosmetic Registration Program database (most VCRP information is publicly available if requested under a Freedom of Information (FOI) request).

5. Campaign for Safe Cosmetics, "A Poison Kiss: The Problem of Lead in Lipstick," October 2007, available at http://www.womensvoices.org/wp-content/uploads/2010/06/PoisonKiss1.pdf.

6. Hepp, N. M., Mindak, W. R., and Cheng, J., “Determination of total lead in lipstick: Development and validation of a microwave-assisted digestion, inductively coupled plasma-mass spectrometric method,” Journal of Cosmetic Science, vol. 60, pp. 405-414, 2009.

7. 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.

8. “Lip Products Brand Shares by Retail Value 2004-2007,” *in* Cosmetics and Toiletries in the U.S., Euromonitor International Ltd., London, May 2008, Table 64, pp. 78-79.

9. Hepp, N. M., “Determination of total lead in 400 lipsticks on the U.S. market using a validated microwave-assisted digestion, inductively coupled plasma-mass spectrometric method,” Journal of Cosmetic Science, vol. 63, pp. 159-176, 2012.

10. Hepp, N. M., Mindak, W. R., Gasper, J. W., Thompson, C. B., and Barrows, J. N., “Survey of cosmetics for arsenic, cadmium, chromium, cobalt, lead, mercury, and nickel content,” Journal of Cosmetic Science, vol. 65, pp. 125-145, 2014.

11. U.S. Food and Drug Administration, “FDA’s Testing of Cosmetics for Arsenic, Cadmium, Chromium, Cobalt, Lead, Mercury, and Nickel Content,” December 2016, available at http://www.fda.gov/Cosmetics/ProductsIngredients/PotentialContaminants/ucm452836.htm.

12. International Cooperation on Cosmetics Regulation, “Considerations on Acceptable Lead Levels in Cosmetic Products,” December 2013, available at http://iccrnet.org/topics/.

13. 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.

14. Hostynek, J. J., “Factors determining percutaneous metal absorption,” Food and Chemical Toxicology, vol. 41, pp. 327-345, 2003.

15. Fullerton, A., Andersen, J. R., and Hoelgaard, A., “Permeation of nickel through human skin in vitro—effect of vehicles,” British Journal of Dermatology, vol. 118, pp. 509-516, 1988.

16. Office of Cosmetics and Colors (HFS-100) Lead in Cosmetics Team, “Exposure to Lead from Cosmetic Lip Products and Externally Applied Cosmetics,” Memorandum to the Administrative Record – Lead in Cosmetics Draft Guidance, August 19, 2016.

17. Loretz, L. J., Api, A. M., Barraj, L. M., Burdick, J., Dressler, W. E., Gettings, S. D., Han Hsu, H., Pan, Y. H. L., Re, T. A., Renskers, K. J., Rothenstein, A.,, Scrafford, C. G., and Sewall, C., “Exposure data for cosmetic products: lipstick, body lotion, and face cream,” Food and Chemical Toxicology, vol. 43, pp. 279-291, 2005.

18. McNamara, C., Rohan, D., Golden, D., Gibney, M., Hall, B., Tozer, S., Safford, B.,

Coroama, M., Leneveu-Duchemin, M. C., and Steiling, W., “Probabilistic modelling of European consumer exposure to cosmetic products,” Food and Chemical Toxicology, vol. 45, pp. 2086-2096, 2007.

19. Hall, B., Tozer, S., Safford, B., Coroama, M., Steiling, W., Leneveu-Duchemin, M. C., McNamara, C., and Gibney, M., “European consumer exposure to cosmetic products, a framework for conducting population exposure assessments,” Food and Chemical Toxicology, vol. 45, pp. 2097-2108, 2007.

20. 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.

21. Carrington, C. D., Bolger, P. M., and Scheuplein, R. J., “Risk analysis of dietary lead exposure,” Food Additives and Contaminants, vol. 13, pp. 61-76, 1996.

22. World Health Organization, “Safety evaluation of certain food additives and contaminants,” prepared by the Fifty-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), WHO Food Additives Series, No. 44, 2000, available at http://www.inchem.org/documents/jecfa/jecmono/v44jec12.htm.

23. World Health Organization, “Safety evaluation of certain food additives and contaminants,” prepared by the Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), WHO Food Additives Series, No. 64, 2011, available at http://whqlibdoc.who.int/publications/2011/9789241660648_eng.pdf.

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

25. 42 CFR Part 493, available at http://www.ecfr.gov.

26. Heitland, P., and Köster, H. D., “Biomonitoring of 37 trace elements in blood samples from inhabitants of northern Germany by ICP–MS,” Journal of Trace Elements in Medicine and Biology, vol. 20, pp. 253–262, 2006.

27. Loretz, L., Api, A. M., Barraj, L., Burdick, J., Davis, D., Dressler, W., Gilberti, E., Jarrett, G., Mann, S., Pan, Y. H. L., Re, T., Renskers, K., Scrafford, C., and Vater, S., “Exposure data for personal care products: Hairspray, spray perfume, liquid foundation, shampoo, body wash, and solid antiperspirant,” Food and Chemical Toxicology, vol. 44, pp. 2008–2018, 2006.

28. 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.

29. 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.

30. 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.