



FDA Publishes Guidance on Heavy Metals in Cosmetics

US FDA, PRODUCTS OF INTEREST

By LANA BECKETT, February 6, 2017

CNN **reported**¹⁾ that the Food and Drug Administration (FDA) has turned a critical eye to lead in cosmetics such as lipstick, eye shadow and shampoo. In a new draft guidance issued in December, the FDA suggested a limit on lead contained in cosmetics marketed in the United States: a maximum of **10 parts per million**²⁾ for lead in lipsticks, lip glosses and lip liners, as well as externally applied cosmetics, such as eye shadows, blushes, body lotions and shampoo.

A **summary document**³⁾ by the FDA stresses that the new guidance "does not establish any rights for any person and is not binding." Instead, the new guidance simply represents the FDA's "current thinking" on the issue of lead in cosmetic products. "Although most cosmetics on the market in the United States generally already contain less than 10 ppm of lead, a small number contained higher amounts, and we are aware that some cosmetics from other countries contain lead at higher levels," the FDA said on its website. "This makes guidance on recommended maximum lead levels all the more important as more products are imported into this country."

More than **99% of the cosmetic lip products and externally applied cosmetics on the US market**⁴⁾ contain lead at levels below 10 ppm, according to the FDA. Testing by the FDA found one eye shadow, Clarins Paris Mono Couleur 19 Ice Blue, and one blush, L'Oreal Lancome Blush Subtil 8 Brun Roche, contained **14 parts per million of lead**⁵⁾.

"In 2011, a Citizen Petition from an association representing the personal care products industry requested that the FDA issue a guidance document limiting lead to 10 ppm in cosmetic lip products and externally applied cosmetics," said Theresa Eisenman, a spokeswoman for the FDA.

The new FDA draft guidance is not a rule that must be followed; it's only a suggestion, said David C. Steinberg, founder of Steinberg & Associates, Inc, a consulting company for the personal care industry which specializes in US regulations for cosmetics and cosmetic chemistry. Steinberg is a former national president of the Society of Cosmetic Chemists, which told CNN it does not comment on industry matters.

The **International Cooperation on Cosmetic Regulation**⁶⁾ (ICCR), which consists of the cosmetic regulatory branch of the FDA and its counterparts in Brazil, Canada, the European Union, and Japan, agreed on the same maximum level of lead when they convened for their annual meeting three years ago, Steinberg said. ICCR works with independent cosmetic industry trade associations to align cosmetic product regulations globally in order to minimize trade barriers while maximizing consumer protections.

Resources for this article

1. reported

<http://www.cnn.com/2016/12/22/health/fda-lead-levels-lipstick-cosmetics/>

2. 10 parts per million

<http://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm452623.htm>

3. summary document

<http://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm452623.htm>

4. 99% of the cosmetic lip products and externally applied cosmetics on the US market

http://www.fda.gov/cosmetics/productsingredients/products/ucm137224.htm#expanded_survey

5. 14 parts per million of lead

<http://www.fda.gov/Cosmetics/ProductsIngredients/PotentialContaminants/ucm452836.htm#S1ES>

6. Steinberg & Associates, Inc

<http://www.steinbergandassociates.com/about2>

7. International Cooperation on Cosmetic Regulation

<http://www.iccrnet.org/search/>