

Council of State and Territorial Disease Epidemiologists (CSTE), supported by CDC, determines which reportable conditions should be designated nationally notifiable and voluntarily submitted to CDC so that information can be shared across jurisdictional boundaries and both surveillance and prevention and control activities can be coordinated at regional and national levels.

CDC requests a three-year approval for a Revision for the National Notifiable Diseases Surveillance System (NNDSS), OMB Control No. 0920-0728, Expiration Date 01/31/2019. This Revision includes requests for approval to receive: (1) Case notification data from the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau (independent nations that operate under a Compact of Free Association

with the United States of America that are commonly referred to as “freely associated states”); (2) case notification data for histoplasmosis which is now under standardized surveillance; and (3) case notification data for all enteric *Escherichia coli* infections should any of them become nationally notifiable or be placed under standardized surveillance. CDC already has approval to receive case notification data for Shiga toxin-producing *Escherichia coli* (STEC) which is nationally notifiable.

Although this Revision includes case notifications that were not part of the last NNDSS Revision, the estimate of the average burden per response based on the burden tables from all of the consolidated applications for states, cities, and territories has not changed. The addition of new diseases and conditions, should they become

nationally notifiable or be placed under standardized surveillance, will not increase the burden since most case notifications are submitted from already existing databases. The burden on the states and cities is estimated to be 10 hours per response and the burden on the territories is estimated to be 5 hours per response. The total burden will increase because of the request to receive case notification data from the freely associated states. The burden on the freely associated states is estimated to be the same as the burden for the territories, 5 hours per response. This is because the methods and systems that the freely associated states use to send case notification data to CDC are nearly the same as the territories.

There will be no costs to respondents other than their time. The estimated annual burden is 29,120 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
States .....	Weekly and Annual .....	50	52	10	26,000
Territories .....	Weekly and Annual .....	5	52	5	1,300
Freely Associated States .....	Weekly and Annual .....	3	52	5	780
Cities .....	Weekly and Annual .....	2	52	10	1,040
Total .....	.....	.....	.....	.....	29,120

**Leroy A. Richardson,**  
 Chief, Information Collection Review Office,  
 Office of Scientific Integrity, Office of the  
 Associate Director for Science, Office of the  
 Director, Centers for Disease Control and  
 Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled, “Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level.” This draft guidance provides a recommended maximum

level of 10 parts per million (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. We consider the recommended maximum lead level to be achievable with the use of good manufacturing practices and consistent with the 10 ppm maximum lead level for similar products recommended by other countries, and we have concluded that the recommended maximum lead level would not pose a health risk.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 21, 2017.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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):* Division of Dockets Management (HFA-305), Food

and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, 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–2014–D–2275 for “Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level; Draft Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Julie N. Barrows, Center for Food Safety and Applied Nutrition (HFS–106), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1119.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled, “Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level.” This draft guidance provides a recommended 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. FDA 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. Additionally, the recommended maximum level is consistent with the 10 ppm maximum lead level for similar products recommended by other countries. This draft guidance does not apply to topically applied products that are classified as drugs or to hair dyes that contain lead acetate as an ingredient.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA’s current thinking on “Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level.” 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.

## **II. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Cosmetics/GuidanceRegulation/default.htm> or <https://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: December 16, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–30781 Filed 12–21–16; 8:45 am]

**BILLING CODE 4164–01–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA–2016–N–2474]

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by January 23, 2017.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0605. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed