

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
Individuals	Cyclosporinosis National Hypothesis Generating Questionnaire.	1,000	1	45/60	750
Total	750

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**

**Centers for Disease Control and
 Prevention**

[60Day-17-0728; Docket No. CDC-2016-0119]

**Proposed Data Collection Submitted
 for Public Comment and
 Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the National Notifiable Diseases Surveillance System (NNDSS). The NNDSS is the nation's public health surveillance system that monitors the occurrence and spread of diseases and conditions that are nationally notifiable or under national surveillance.

DATES: Written comments must be received on or before February 21, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0119 by any of the following methods:

- *Federal eRulemaking Portal:* Regulations.gov. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and

Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

National Notifiable Diseases Surveillance System (OMB Control Number 0920-0728, expires 1/31/2019)—Revision—Center for Surveillance, Epidemiology and Laboratory Services, CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Public Health Services Act (42 U.S.C. 241) authorizes CDC to disseminate nationally notifiable condition information. The Nationally Notifiable Diseases Surveillance System (NNDSS) is based on data collected at the state, territorial and local levels as a result of legislation and regulations in those jurisdictions that require health care providers, medical laboratories, and other entities to submit health-related data on reportable conditions to public health departments. These reportable conditions, which include infectious and non-infectious diseases, vary by jurisdiction depending upon each jurisdiction's health priorities and needs. Infectious disease agents and environmental hazards often cross geographical boundaries. Each year, the

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.

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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

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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