

## 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.

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

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 Chief, Information Collection Review Office,  
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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