

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.

[FR Doc. 2016-30778 Filed 12-21-16; 8:45 am]

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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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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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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