

Elimination of Tuberculosis,  
Department of Health and Human  
Services, 1600 Clifton Road NE.,  
Mailstop E-10, Atlanta, Georgia 30333,  
telephone 404/639-8000 or fax 404/  
639-8600.

The Director, Management Analysis  
and Services Office, has been delegated  
the authority to sign **Federal Register**  
notices pertaining to announcements of  
meetings and other committee  
management activities, for both the  
Centers for Disease Control and  
Prevention and the Agency for Toxic  
Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services  
Office, Centers for Disease Control and  
Prevention.*

[FR Doc. 2015-07541 Filed 4-1-15; 8:45 am]

**BILLING CODE CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-D-0045]

#### Abuse-Deterrent Opioids—Evaluation and Labeling; Guidance for Industry; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug  
Administration (FDA) is announcing the  
availability of a guidance for industry  
entitled “Abuse-Deterrent Opioids—  
Evaluation and Labeling”. This  
guidance explains FDA’s current  
thinking about the studies that should  
be conducted to demonstrate that a  
given formulation has abuse-deterrent  
properties. This guidance also makes  
recommendations about how those  
studies should be performed and  
evaluated, and discusses how to  
describe those studies and their  
implications in product labeling. It is  
intended to assist sponsors who wish to  
develop opioid drug products with  
potentially abuse-deterrent properties  
and is not intended to apply to products  
that are not opioids or opioid products  
that do not have the potential for abuse.

**DATES:** Submit either electronic or  
written comments on Agency guidances  
at any time.

**ADDRESSES:** Submit written requests for  
single copies of this guidance to the  
Division of Drug Information, Center for  
Drug Evaluation and Research, Food  
and Drug Administration, 10001 New  
Hampshire Ave., Hillandale Building,  
4th Floor, Silver Spring, MD 20993–

0002. Send one self-addressed adhesive  
label to assist that office in processing  
your requests. See the **SUPPLEMENTARY  
INFORMATION** section for electronic  
access to the guidance document.

Submit electronic comments on the  
guidance to <http://www.regulations.gov>.  
Submit written comments to the  
Division of Dockets Management (HFA–  
305), Food and Drug Administration,  
5630 Fishers Lane, Rm. 1061, Rockville,  
MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Brutrinia D. Cain, Center for Drug  
Evaluation and Research, Food and  
Drug Administration, 10903 New  
Hampshire Ave., Silver Spring, MD  
20993, 301-796-4633, [Brutrinia.Cain@fda.hhs.gov](mailto:Brutrinia.Cain@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of  
a guidance for industry entitled “Abuse-  
Deterrent Opioids—Evaluation and  
Labeling.” Prescription opioid products  
are an important component of modern  
pain management. However, abuse and  
misuse of these products have created a  
serious and growing public health  
problem. One potentially important step  
towards the goal of creating safer opioid  
analgesics has been the development of  
opioids that are formulated with some  
properties intended to deter abuse. FDA  
considers development of these  
products a high public health priority.

The guidance is intended to provide  
industry with a framework for  
evaluating and labeling abuse-deterrent  
opioid products. The guidance  
discusses how the potentially abuse-  
deterrent properties of an opioid  
analgesic formulated to deter abuse  
should be studied, specifically  
addressing in vitro studies,  
pharmacokinetic studies, clinical abuse  
potential studies, and postmarket  
studies. The guidance also describes the  
types of information that may be  
suitable for inclusion in labeling.

Providing a clear framework for the  
evaluation and labeling of the abuse-  
deterrent properties of opioid analgesics  
intended to deter abuse should help to  
incentivize the development of safer,  
less abusable opioid analgesics, and  
should also facilitate the dissemination  
of fair and accurate information  
regarding such products.

In the **Federal Register** of January 14,  
2013 (78 FR 2676), FDA announced the  
availability of a draft version of this  
guidance and provided interested  
parties an opportunity to submit  
comments. The Agency has carefully  
reviewed and considered the comments  
it received in developing this final

version of the guidance. The Agency has  
made revisions to the guidance as it  
deemed appropriate.

This guidance is being issued  
consistent with FDA’s good guidance  
practices regulation (21 CFR 10.115).  
The guidance represents the current  
thinking of FDA on the evaluation and  
labeling of abuse-deterrent opioids. 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. Comments

Interested persons may submit either  
electronic comments regarding this  
document to <http://www.regulations.gov>  
or written comments to the Division of  
Dockets Management (see **ADDRESSES**). It  
is only necessary to send one set of  
comments. Identify comments with the  
docket number found in brackets in the  
heading of this document. Received  
comments may be seen in the Division  
of Dockets Management between 9 a.m.  
and 4 p.m., Monday through Friday, and  
will be posted to the docket at <http://www.regulations.gov>.

##### III. Electronic Access

Persons with access to the Internet  
may obtain the document at either  
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 27, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-07562 Filed 4-1-15; 8:45 am]

**BILLING CODE CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0005]

#### Agency Information Collection Activities: Application for Family Unity Benefits, Form I-817; Revision of a Currently Approved Collection

**AGENCY:** U.S. Citizenship and  
Immigration Services (USCIS),  
Department of Homeland Security  
(DHS).

**ACTION:** 60-Day notice.

**SUMMARY:** DHS, USCIS invites the  
general public and other Federal  
agencies to comment upon this  
proposed revision of a currently