

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.

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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.

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]

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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

approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until June 1, 2015.

ADDRESSES: All submissions received must include the OMB Control Number 1615-0005 in the subject box, the agency name and Docket ID USCIS-2009-0021. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at www.regulations.gov under e-Docket ID number USCIS-2009-0021;

(2) *Email.* Submit comments to USCISFRComment@uscis.dhs.gov;

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529-2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Laura Dawkins, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529-2140, telephone number 202-272-8377 (comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at <http://www.uscis.gov>, or call the USCIS National Customer Service Center at 800-375-5283 (TTY 800-767-1833).

SUPPLEMENTARY INFORMATION:

Comments: You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at <http://www.regulations.gov> and enter USCIS-2009-0021 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to

consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Family Unity Benefits.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I-817; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* *Primary:* Individuals or households: The information collected will be used to determine whether the applicant meets the eligibility requirements for benefits under 8 CFR 236.14 and 245a.33.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I-817 is approximately 2,557 and the estimated hour burden per response is 2 hours per response; and the estimated number of respondents providing biometrics is 2,557 and the estimated hour burden per response is 1.17 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 8,106 hours.

Dated: March 27, 2015.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2015-07506 Filed 4-1-15; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5843-N-04]

Implementation of the Privacy Act of 1974, as Amended; New System of Records, the Housing Search Process for Racial and Ethnic Minorities Evaluation Data Files

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: New system of records.

SUMMARY: The Department's Office of Policy Development and Research (PD&R) is proposing to create a new system of records, the "Housing Search Process for Racial and Ethnic Minorities Evaluation Data Files." The Department's Office of PD&R is responsible for maintaining current information on housing needs, market conditions and existing programs, as well as conducting research on priority housing and community development issues.

The principal purpose of the evaluation of the Housing Search Process for Racial and Ethnic Minorities is to: Help guide the Department's research toward a more comprehensive understanding of the rental housing search processes for individual households; Make informed decisions on the development of more effective enforcement strategies to combat discriminatory practices; Identify ways to expand housing opportunities for racial and ethnic minorities. Further, HUD's Office of Housing Counseling for rental housing assistance, and the Office of Housing Choice Vouchers, among others will leverage the outcome study results for policy development and best practices aimed to "build inclusive and sustainable communities free from discrimination", and to identify and correct barriers that racial and ethnic minorities may experience in the rental housing market. Finally, this study will allow the Department to leverage its own regular data collection efforts, like