

opioid products in non-opioid tolerant and inappropriately selected individuals; (2) abuse; (3) misuse; and (4) overdose, both accidental and intentional. REMS for these opioids would likely include elements to assure safe use to ensure that prescribers, dispensers, and patients are aware of and understand the risks and proper use of these products. The opioid drugs expected to be subject to REMS are widely prescribed by a large number of physicians who practice in a wide variety of areas. A REMS that will adequately manage the risks of these products without unduly burdening the health care system or reducing patient access to these medications must be carefully designed. Recognizing this challenge, we identified several specific areas in which FDA wishes to obtain information and public comment in our April 2009 notice of public meeting.

Interested persons were originally given until June 30, 2009, to comment. As a result of continued public interest, FDA is reopening the comment period until October 19, 2010 to allow interested persons additional time to provide information and share views on this topic.

II. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.regulations.gov> or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Dated: October 9, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: OMB-48, InfoPass System; New Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: OMB-48, InfoPass System.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on July 28, 2009, at 74 FR 37234, allowing for a 60-day public comment period. USCIS did not receive any comments.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until November 18, 2009. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, Clearance Office, 111 Massachusetts Avenue, Washington, DC 20529-2210. Comments may also be submitted to DHS via facsimile to 202-272-8352 or via e-mail at rfs.regs@dhs.gov, and to the OMB USCIS Desk Officer via facsimile to 202-395-5806 or via e-mail at oir_submission@omb.eop.gov.

When submitting comments by e-mail, please make sure to add OMB-48 in the subject box. 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 agencies 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:* New Information collection.

(2) *Title of the Form/Collection:* InfoPass System.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* No Agency Form Number; File No. OMB-48. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. The InfoPass system allows an applicant or petitioner to schedule an interview appointment with USCIS through USCIS' Internet Web site.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,043,319 responses at 6 minutes (.10) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 104,332 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: <http://www.regulations.gov/>

We may also be contacted at: USCIS, Regulatory Products Division, 111 Massachusetts Avenue, NW., Washington, DC 20529-2210, Telephone number 202-272-8377.

Dated: October 14, 2009.

Stephen Tarragon,

Deputy Chief, Regulatory Products Division, U.S. Citizenship and Immigration Services.

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