

entitled "Providing Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports." FDA published a notice of availability of the draft guidance in the **Federal Register** of June 24, 2003 (68 FR 37504). The agency is taking this action in response to a request for an extension of the comment period.

**DATES:** Submit written or electronic comments on the draft guidance by December 16, 2003. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Randy Levin, CDER (HFD-140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5411, [Levinr@cder.fda.gov](mailto:Levinr@cder.fda.gov), or Michael Fauntleroy, CBER (HFM-588), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5132, [Fauntleroy@cber.fda.gov](mailto:Fauntleroy@cber.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of June 24, 2003 (68 FR 37504), FDA published a notice announcing the availability of a draft guidance for industry entitled "Providing Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports." This draft guidance discusses issues related to the electronic submission of postmarketing periodic adverse drug experience reports for drug products marketed for human use with new drug applications (NDAs) and abbreviated new drug applications (ANDAs), and therapeutic and blood products

marketed for human use with biologics license applications (BLAs). The draft guidance does not apply to vaccines, whole blood, or components of whole blood. Interested persons were given until August 25, 2003, to submit written or electronic comments on the draft guidance. In response to a comment requesting an extension of the comment period, FDA has decided to reopen the comment period on the draft guidance until December 16, 2003, to allow interested persons additional time to submit comments.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance on or before December 16, 2003. Two copies of any mailed comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm>.

Dated: October 8, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Bureau of Citizenship and Immigration Services**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**ACTION:** 30-Day Notice of Information Collection Under Review: Petition for Alien Relative; Form I-130.

The Department of Homeland Security, Bureau of Citizenship and Immigration Services (BCIS), 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 BCIS published a **Federal Register** notice on May 9, 2003 at 68 FR 25054, to solicit public comments for a 60-day period regarding the extension of Form I-130 (Petition for Alien Relative). The BCIS have received no public comment on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until November 17, 2003. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street, NW., Room 10235, Washington, DC 20530; Attention: Department of Homeland Security Desk Officer.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information 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:* Extension of currently approved collection.

(2) *Title of the Form/Collection:* Petition for Alien Relative.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I-130, Bureau of Citizenship and Immigration Services, Department of Homeland Security.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or

Households. The information collected on this form will be used by BCIS to determine eligibility for benefits sought for relatives of U.S. citizens and lawful permanent residents.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 183,034 responses at 30 minutes (.50 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 91,517 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202-514-3291, Director, Regulations and Forms Services Division, U.S. Department of Homeland Security, 425 I Street, NW., Suite 4034, Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Ms. Theresa O'Malley, Chief Information Officer, U.S. Department of Homeland Security, Regional Office Building 3, 7th and D Streets, SW., Suite 4636-26, Washington, DC 20202.

Dated: October 9, 2003.

**Richard A. Sloan,**

*Department Clearance Officer, U.S. Department of Homeland Security, Bureau of Citizenship and Immigration Services.*  
[FR Doc. 03-26221 Filed 10-16-03; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Bureau of Customs and Border Protection

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**ACTION:** 30-Day notice of information collection under review: visa waiver program passenger arrival and department data (file No. OMB-32).

The Department of Homeland Security, Bureau of Customs and Border Protection (CBP), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and temporary clearance in accordance with the Paperwork Reduction Act of 1995. The legacy Immigration and Naturalization Service (INS) published an interim rule

containing the proposed information collection in the **Federal Register** on October 11, 2002 at 67 FR 63246. The interim rule also solicited public review and comments on the information collection for a period of 30 days. No comments were received. The INS received temporary OMB approval of this information collection.

The purpose of this notice is to allow an additional 30 days for public comments to extend the use of this information collection for a temporary approval. Comments are encouraged and will be accepted until November 17, 2003. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, 725 17th Street, NW., Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information 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:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Visa Waiver Program Passenger Arrival and Departure Date.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* No Agency Form Number (file No. OMB-32); Bureau of Customs

and Border Protection, Department of Homeland Security.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Section 217(h) of the INA requires an automated entry and exit control system by specifying those passenger data elements that must be electronically transmitted to the CBP by carriers seeking to transport Visa Waiver Program passengers into and out of the U.S.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 600 responses at 5 minutes (.083 hours) per response. Frequency of response is 365.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 36,500 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202-514-3291, Director, Regulations and Forms Services Division, Department of Homeland Security, Room 4034, 425 I Street, NW., Washington, DC 20536.

Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Ms. Theresa O'Malley, Chief Information Officer, Department of Homeland Security, Regional Office Building 3, 7th and D Streets, SW., Suite 4636-26, Washington, DC 20202.

Dated: October 9, 2003.

**Richard A. Sloan,**

*Department Clearance Officer, Department of Homeland Security, Bureau of Customs and Border Protection.*

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BILLING CODE 4410-10-M

## DEPARTMENT OF HOMELAND SECURITY

### Bureau of Customs and Border Protection

#### Agency Information Collection Activities; Proposed Collection; Comment Request

**ACTION:** 30-Day notice of information collection under review: passenger list, crew list; Form I-418.

The Bureau of Customs and Border Protection (CBP) has submitted the