

that describes the type of data FDA recommends a manufacturer provide to address this issue (this section replaces the previous Retrieval Study section). When final, this draft guidance document will supersede "Guidance for Saline, Silicone Gel, and Alternative Breast Implants," dated February 11, 2003.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on "Saline, Silicone Gel, and Alternative Breast Implants." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

To receive "Saline, Silicone Gel, and Alternative Breast Implants," you may either send a fax request to 301-443-8818 to receive a paper copy of the document, or send an e-mail request to [GWA@CDRH.FDA.GOV](mailto:GWA@CDRH.FDA.GOV) to receive a paper copy or an electronic copy. Please use the document number (1239) to identify the guidance you are requesting.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of cleared submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

## IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and

Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501-3520) (the PRA). The collections of information addressed in Sections 3 through 10 of the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB No. 0910-0231). The labeling provisions addressed in Section 11 of the guidance document have been approved under OMB No. 0910-0485.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document on or before April 12, 2004. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 7, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Bureau of Citizenship and Immigration Services

#### Agency Information Collection Activities: Comment Request

**ACTION:** 60-Day Notice of Information Collection Under Review; National Interest Waivers; Supplemental Evidence to I-140 and I-485.

The Department of Homeland Security, Bureau of Citizenship and Immigrations Services (CIS) has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty day until March 15, 2004.

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 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 of 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 collection.

(2) *Title of the Form/Collection:* National Interest Waivers; Supplemental Evidence to I-140 and I-485.

(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-22 Bureau of Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individual or Households. The information collected via the submitted supplemental documentation will be used by the Bureau of Citizenship and Immigration Services to determine eligibility for the request national interest waiver and to finalize the request for adjustment to lawful permanent resident status.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 8,000 responses at one (1) hour per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 8,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or a additional information, please contact Richard A. Sloan (202) 514-3291, Director, Regulations and Forms Services Division, Department of Homeland Security, 425 I Street, NW., Room 4304, 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: Mr. Steve Cooper, PRA Clearance Officer, Department of Homeland Security, Office of the Chief Information Officer, Regional Office Building 3, 7th and D Streets, SW., Suite 4636-26, Washington, DC 20202.

Dated: December 12, 2003.

**Richard A. Sloan,**

*Department Clearance Officer, Department of Homeland Security, Bureau of Citizenship and Immigration Services.*

[FR Doc. 04-283 Filed 1-12-04; 8:45 am]

**BILLING CODE 4410-10-M**

## DEPARTMENT OF HOMELAND SECURITY

### Bureau of Citizenship and Immigration Services

#### Agency Information Collection Activities: Comment Request

**ACTION:** 60-Day Notice of Information Collection Under Review; Application for Issuance or Replacement of Northern Mariana Card; Form I-777.

The Department of Homeland Security (DHS) and the Bureau of Citizenship and Immigration Services (CIS), has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until March 15, 2004.

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 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:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Application for Issuance or Replacement of Northern Mariana Card.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-777. Bureau of 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. This information collection is used by applicants to apply for a Northern Mariana identification card if they received United States citizenship pursuant to Pub. L. 94-241 (Covenant to Establish a Commonwealth of the Northern Mariana Island).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 100 responses at 30 minutes (.50 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 50 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: Mr. Steve Cooper, PRA Clearance Officer, Department of Homeland Security, Office of the Chief Information Officer, Regional Office Building 3, 7th and D Streets, SW., Suite 4636-26, Washington, DC 20202.

Dated: December 12, 2003.

**Richard A. Sloan,**

*Department Clearance Officer, Department of Homeland Security, Bureau of Citizenship and Immigration Services.*

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## DEPARTMENT OF HOMELAND SECURITY

### Bureau of Citizenship and Immigration Services

#### Agency Information Collection Activities: Extension of Existing Collection; Comment Request

**ACTION:** 60-Day Notice of Information Collection Under Review; Generic Clearance of Customer Service Surveys.

The Department of Homeland Security, Bureau of Citizenship and Immigration Services (CIS), has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until March 15, 2004.

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 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:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Generic Clearance of Customer Service Surveys.

(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-09). Bureau of Citizenship and Immigration Services.