

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0453]

#### **Draft Guidance for Industry and Food and Drug Administration Staff; 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device; Availability; Reopening of Comment Period**

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

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until November 28, 2011, the comment period for the notice entitled "Draft Guidance for Industry and Food and Drug Administration Staff; 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device; Availability," that appeared in the **Federal Register** of July 27, 2011 (76 FR 44935). In that document, FDA announced the availability of a draft guidance for industry and FDA staff and requested comments. The Agency is taking this action to allow interested persons additional time to submit comments.

**DATES:** Submit either electronic or written comments by November 28, 2011.

**ADDRESSES:** Submit electronic comments on the draft guidance to 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:**

Michael J. Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1615, Silver Spring, MD 20993-0002, (301) 796-6283; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, (301) 827-6210.

#### **I. Background**

In the **Federal Register** of July 27, 2011 (76 FR 44935), FDA published a notice with a 90-day comment period to request comments on the draft guidance for industry and FDA staff entitled "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device." Comments on the draft guidance will assist FDA in the

development of a final guidance for industry and FDA staff.

FDA is reopening the comment period for the notice until November 28, 2011. The Agency believes that this will allow adequate time for interested persons to submit comments without significantly delaying action by the Agency.

#### **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

#### **III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health (CDRH) guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from the Center for Biologics Evaluation and Research at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device" from CDRH, you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to (301) 847-8149 to receive a hard copy. Please use the document number 1793 to identify the guidance you are requesting.

Dated: November 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-28875 Filed 11-7-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Citizenship and Immigration Services

#### **Agency Information Collection Activities: Form I-817, Extension of a Currently Approved Information Collection; Comment Request**

**ACTION:** 30-Day Notice of Information Collection Under Review: Form I-817,

Application for Family Unity Benefits; OMB Control No. 1615-0005.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting 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. An information collection notice was previously published in the **Federal Register** on August 12, 2011, at 76 FR 50237, allowing for a 60-day public comment period. USCIS did not receive any comments on the extension of 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 December 8, 2011. 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 Management and Budget (OMB) USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, Office of the Executive Secretariat, 20 Massachusetts Avenue NW., Washington, DC 20529-2020. Comments may also be submitted to DHS via facsimile to (202) 272-0997 or via email at [rfs.regs@dhs.gov](mailto:rfs.regs@dhs.gov), and to the OMB USCIS Desk Officer via facsimile at (202) 395-5806 or via email at [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). When submitting comments by email please make sure to add OMB Control Number 1615-0005 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:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:*

Application for Family Unity Benefits.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-817; U.S. Citizenship and Immigration Services (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:* 1,750 responses at 2 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 3,500 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, 20 Massachusetts Avenue NW., Washington, DC 20529-2020; Telephone (202) 272-8377.

Dated: November 3, 2011.

**Sunday Aigbe,**

*Chief, Regulatory Products Division, Office of the Executive Secretariat, U.S. Citizenship and Immigration Services, Department of Homeland Security.*

[FR Doc. 2011-28954 Filed 11-7-11; 8:45 am]

BILLING CODE 9111-97-P

#### DEPARTMENT OF HOMELAND SECURITY

##### U.S. Citizenship and Immigration Services

##### Agency Information Collection Activities: Form N-400, Extension of a Currently Approved Information Collection; Comment Request

**ACTION:** 30-Day Notice of Information Collection Under Review: Form N-400, Application for Naturalization; OMB Control No. 1615-0052.

The Department of Homeland Security, U.S. Citizenship and

Immigration Services (USCIS) will be submitting 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. An information collection notice was previously published in the **Federal Register** on August 12, 2011, at 76 FR 50236, allowing for a 60-day public comment period. USCIS did not receive any comments on the 60-day notice.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until December 8, 2011. 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 Management and Budget (OMB), USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, 20 Massachusetts Avenue, Washington, DC 20529-2020. Comments may also be submitted to DHS via facsimile to (202) 272-0997 or via email at [uscisfrcomment@dhs.gov](mailto:uscisfrcomment@dhs.gov) and to the OMB USCIS Desk Officer via facsimile at (202) 395-5806 or via email at [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov).

When submitting comments by email please make sure to add OMB Control Number 1615-0052 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 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 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 an existing information collection.

(2) *Title of the Form/Collection:* Application for Naturalization.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N-400. 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.* USCIS uses the information on this form to determine an applicant's eligibility for naturalization.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 693,890 responses at 6 hours and 8 minutes (6.13 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 4,253,545 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, 20 Massachusetts Avenue, NW., Washington, DC 20529-2020, telephone number (202) 272-8377.

Dated: November 3, 2011.

**Sunday Aigbe,**

*Chief, Regulatory Products Division, Office of the Executive Secretariat, U.S. Citizenship and Immigration Services, Department of Homeland Security.*

[FR Doc. 2011-28946 Filed 11-7-11; 8:45 am]

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#### DEPARTMENT OF HOMELAND SECURITY

##### U.S. Citizenship and Immigration Services

##### Agency Information Collection Activities: Form I-192, Extension of a Currently Approved Information Collection; Comment Request

**ACTION:** 30-Day Notice of Information Collection Under Review: Form I-192, Application for Advance Permission to Enter as Nonimmigrant (Pursuant to 212(d)(3) of the Immigration and Nationality Act); OMB Control No. 1615-0017.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information