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Draft Guidance for Industry and Food and Drug Administration Staff; 510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device;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Food and Drug Administration (FDA) is reopening until November 28, 2011, the comment period for the notice entitled ''Draft Guidance for Industry and Food and Drug Administration Staff; 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device;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 In that document, FDA announced the availability of a draft guidance for industry and FDA staff and requested comments.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ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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of July 27, 2011 (76 FR 44935), FDA published a notice with a 90-day comment period to request comments on the draft guidance for industry and FDA staff entitled ''510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device.'' Comments on the draft guidance will assist FDA in the development of a final guidance for industry and FDA staff.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* 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.

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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,* and to the OMB USCIS Desk Officer via facsimile at (202) 395–5806 or via email at *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