Dated: November 9, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–28849 Filed 11–15–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

External Defibrillators; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop: FDA Public Workshop on External Defibrillators. The purpose of the public workshop is to share FDA's understanding of the risks and benefits of external defibrillators, to clarify FDA's current expectations for how industry should identify, report, and take action on problems observed with these devices, and to promote innovation for next-generation devices that will bring safer, more effective external defibrillators to market.

Dates and Time: The public workshop will be held on December 15, 2010, from 8 a.m. to 5:30 p.m., and on December 16, 2010, from 8 a.m. to 2 p.m. Persons interested in attending this public workshop must register by 5 p.m. on December 8, 2010.

Location: The public workshop will be held in the Great Room at the Food and Drug Administration, White Oak Campus, Bldg. 31, 10903 New Hampshire Ave., Silver Spring, MD 20903.

Contact: Megan Moynahan, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5404, Silver Spring, MD 20903, 301–796–5435, FAX: 301–847–8510, or e-mail: *Megan.Moynahan@fda.hhs.gov.*

Registration and Requests for Oral Presentations: Registration is free and will be on a first-come, first-served basis. To register for the public workshop, please visit the following Web site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm232062.htm* (or go the FDA Medical Devices New & Events—Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, e-mail, and telephone number. For those without Internet access, please call the contact person to register. Registration requests should be received by 5 p.m. on December 8, 2010. Early registration is recommended because seating is limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

Registrants requesting to present written material or to make oral presentations at the public workshop, please call the contact person by November 29, 2010.

If you need special accommodations due to a disability, please contact Susan Monahan (e-mail: *Susan.Monahan@fda.hhs.gov*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

External defibrillators (including automated external defibrillators (AEDs)) are life-saving devices designed to restore normal heart rhythms following sudden cardiac arrest. Each year, nearly 300,000 Americans collapse from sudden cardiac arrest. In sudden cardiac arrest, the heart unexpectedly stops pumping blood to the body. When normal heart rhythms are not restored quickly, sudden cardiac arrest can cause death.

External defibrillators are important, life-saving devices. However, over the past 5 years we have seen persistent safety problems with all types of external defibrillators, across all manufacturers of these devices. From January 1, 2005, to July 10, 2010, there were a total of 68 recalls, of which 9 occurred in 2005 increasing to 17 in 2009 (the last complete year for which data are available). During this period, FDA received over 28,000 medical device reports (MDRs), of which 4,210 occurred in 2005 increasing to 7,807 in 2009 (the last complete year for which data are available). FDA conducted multiple inspections of all external defibrillator manufacturers throughout this time period.

Many of the types of problems we have identified are preventable, correctable, and impact patient safety. As part of a comprehensive review, FDA identified several industry practices that have contributed to these persistent safety risks including industry practices for designing and manufacturing defibrillators, handling user complaints, conducting recalls, and communicating with users. In some cases, these practices can contribute to device performance problems, place undue burden on users, and put patients at risk.

To date, FDA has addressed individual device problems on a case-by-case basis. However, our analysis of MDRs, recalls, and inspections confirms that common problems persist across all types of external defibrillators and all manufacturers. One purpose of the public workshop is to share FDA's understanding of the risks and benefits of external defibrillators and to clarify FDA's current expectations for how industry should identify, report, and take action on problems observed with these devices.

In addition, to promote innovation and to better understand patient outcomes, FDA is collaborating with the University of Colorado's Department of Emergency Medicine and the Centers for Disease Control and Prevention (CDC) to develop a multi-city AED registry that will link with the CDC-funded Cardiac Arrest Registry to Enhance Survival (CARES). The registry will provide the infrastructure to foster the development of innovative AED features such as automated integration into local 9–1–1 systems. FDA will work with multiple stakeholders to facilitate the development of next-generation defibrillators, enhance surveillance of defibrillators in community settings, and improve the rapid delivery of treatment for sudden cardiac arrest patients. One purpose of the public workshop on December 15 and 16, 2010, is to advance these efforts by bringing together government, industry, academia, and users, including clinicians and consumers, to share perspectives.

II. Topics for Discussion at the Public Workshop

The public workshop will be organized to allow facilitated discussion by industry, academia, clinicians, users, and regulators on the following broad topic areas:

1. What are the nature, scope, and impact of external defibrillator problems that have been observed? What are the root causes of these problems?

2. How should problems with external defibrillators be identified, reported, and acted upon by industry and users?

3. What factors or criteria should be considered when designing external defibrillators for use in different environments (hospital, community, home)?

4. What features of next generation devices can be defined that will increase the diffusion of new technologies, enhance device interoperability, and improve ease of use?

5. How might device registries improve our ability to identify early device performance signals, or enhance the use of external defibrillators?

III. Transcripts

Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857. A link to the transcripts will also be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated: November 9, 2010.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–28763 Filed 11–15–10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–566, Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Form I–566, Interagency Record of Individual Requesting Change/Adjustment To or From A or G Status or Requesting A, G, or NATO Dependent Employment Authorization; OMB Control No. 1615–0027.

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. The information collection was previously published in the **Federal Register** on August 26, 2010, at 75 FR 52538, allowing for a 60-day public comment period. USCIS did not receive any comments for 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 16, 2010. 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 202–272–8352 or via e-mail 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 e-mail please make sure to add OMB Control Number 1615–0027 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:* Interagency Record of Individual Requesting Change/Adjustment To or From A or G Status or Requesting A, G, or NATO Dependent Employment Authorization.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–566; 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.* This information collection facilitates processing of applications for benefits filed by dependents of diplomats, international organizations, and NATO personnel by U.S. Citizenship and Immigration Services, and the Department of State.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 5,800 responses at 15 minutes (.25) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,450 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 9, 2010.

Stephen Tarragon,

Deputy Chief, Regulatory Products Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–290B, Extension of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection under Review: Form I–290B, Notice of Appeal to the Office of Administrative Appeals; OMB Control No.1615–0095.

The Department of Homeland Security, U.S. Citizenship and Immigration Services will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until January 18, 2011.

During this 60-day period, USCIS will be evaluating whether to revise the Form I–290B. Should USCIS decide to revise the Form I–290B it will advise the public when we publish the 30-day