Submit written comments on the 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*.

FOR FURTHER INFORMATION CONTACT: Peter L. Hudson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 25, 2004 (69 FR 8667), FDA published a proposed rule to reclassify two embolization devices from class III (premarket approval) into class II (special controls). The agency is also changing the names and revising the identifications of these devices. The vascular embolization device (previously the arterial embolization device) is intended to control hemorrhaging due to aneurysms, certain types of tumors, and arteriovenous malformations. The neurovascular embolization device (previously the artificial embolization device) is intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations.

FDA revised a November 1, 2002, guidance document entitled ''Guidance for Neurological Embolization Devices'' and published it in the **Federal Register** of February 25, 2004 (69 FR 9667) as a draft class II special controls guidance document to support the reclassification of these device types. Interested persons were invited to comment on the draft guidance by May 25, 2004. FDA received one comment. The comment was supportive of the guidance document but made some suggestions on the guidance's content. FDA considered the suggestions and made appropriate revisions. FDA is now identifying the guidance document entitled ''Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices'' as the guidance document that will serve as the special control for these devices.

The guidance document provides a means by which a vascular embolization device or a neurovascular embolization device may comply with the requirement of special controls for class II devices. Following the effective date of the final reclassification rule, any firm submitting a premarket notification (510(k)) for a vascular embolization device or a neurovascular embolization device will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

We are also withdrawing the draft guidance document entitled ''Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model'' because it contains outdated information. Archived copies of CDRH guidance documents that have been withdrawn are available from the DSMICA (see **ADDRESSES**).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on vascular and neurovascular embolization devices. 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 the approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive a copy of the guidance entitled ''Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1234) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance also may 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 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*.

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 U.S.C. 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing 510(k) submissions (21 CFR part 807, subpart E, OMB control number 0910–0120) and the regulations governing good manufacturing practices (quality system regulation) (21 CFR part 820, OMB control number 0910–0073). The labeling provisions addressed in the guidance document have been approved by OMB under the PRA, OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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: December 15, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–28438 Filed 12–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1558–DR]

West Virginia; Amendment No. 7 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of West Virginia (FEMA–1558–DR), dated September 20, 2004, and related determinations.

EFFECTIVE DATE: December 17, 2004.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated December 17, 2004, the President amended the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act), in a letter to Michael D. Brown, Under Secretary for Emergency Preparedness and Response, Federal Emergency Management Agency, Department of Homeland Security as follows:

I have determined that the damage in certain areas of the State of West Virginia, resulting from severe storms, flooding, and landslides on September 16–27, 2004, is of sufficient severity and magnitude that special conditions are warranted regarding the cost sharing arrangements concerning Federal funds provided under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act).

Therefore, I amend my declaration of September 20, 2004, to authorize Federal funds for Public Assistance Categories A and B (debris removal and emergency protective measures) at 100 percent of total eligible costs for emergency work performed for a selected period of up to 72 hours. Only work performed during the selected 72-hour period will be reimbursed at 100 percent. Each applicant may select its own 72-hour periods and the periods may be different for Categories A and B. The 72 hours must be one continuous period within a window starting at 12:01 a.m. of the first day of the incident period through 11:59 p.m. of the fourteenth full day following the declaration.

This adjustment to State and local cost sharing applies only to debris removal and emergency protective measures (Categories A and B) under the Public Assistance program costs eligible for such adjustments under the law. The law specifically prohibits a similar adjustment for funds provided to States for Other Needs Assistance (Section 408), and the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

Please notify the Governor of West Virginia and the Federal Coordinating Officer of these amendments to my major disaster declarations.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 04–28472 Filed 12–28–04; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4955–N–02]

Emergency Capital Repair Grants for Multifamily Housing Projects Designated for Occupancy by the Elderly; Supplemental Notice

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: On December 16, 2004, HUD published a notice announcing the availability of up to $10 million in grant funds to make emergency capital repairs to eligible multifamily projects that are owned by private nonprofit entities and designated for occupancy by elderly tenants. The December 16, 2004, notice provides instructions for owners to request the funding and instructions for the HUD field offices to process the request. This notice supplements the December 16, 2004, notice by providing additional information regarding the information collection requirements contained in that notice and republishes Appendix 1, the Rental Use Agreement.

DATES: *Effective Date:* This notice does not change the effective date of HUD's December 16, 2004, notice, which was effective upon publication.

FOR FURTHER INFORMATION CONTACT: Aretha Williams, Director, Grant Policy and Management Division, Office of Housing, Room 6142, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone 202–708–3000 (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the toll-free Federal Information Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: On December 16, 2004 (69 FR 75418), HUD published a notice announcing the availability of up to $10 million in grant funds to make emergency capital repairs to eligible multifamily projects that are owned by private nonprofit entities and designated for occupancy by elderly tenants. The capital repair needs must relate to items that present an immediate threat to the health, safety, and quality of life of the tenants. The intent of these grants is to provide one-time assistance for emergency items that could not be absorbed within the project's operating budget, and where the tenants continued occupancy in the immediate near future would be called into question by a delay in initiating the proposed cure. The notice provides instructions for owners to request the funding and instructions for the HUD field offices to process the request.

This notice supplements the December 16, 2004, notice by providing the following additional information regarding the information collection requirements contained in that notice. Specifically, HUD wishes to advise the public that the information collection requirements contained in the December 16, 2004, notice have been submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and OMB approval is pending. In accordance with the Paperwork Reduction Act, HUD may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number. Accordingly, HUD is republishing Appendix 1, the Rental Use Agreement. Once provided, HUD will announce the OMB control number to the public.

Dated: December 22, 2004.

Aaron Santa Anna,

Assistant General Counsel for Regulations.