

20447, Attn: ACF Reports Clearance Officer. E-mail address: [grjohnson@acf.hhs.gov](mailto:grjohnson@acf.hhs.gov).

**OMB Comment:** OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF, E-mail address: [Katherine\\_t.tastrich@eop.gov](mailto:Katherine_t.tastrich@eop.gov).

Dated: December 22, 2004.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 04-28464 Filed 12-28-04; 8:45 am]

BILLING CODE 4184-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0509]

#### **Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association; Extension of Comment Period**

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

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

**SUMMARY:** The Food and Drug Administration (FDA) is extending to January 25, 2005, the comment period for the notice that appeared in the **Federal Register** of November 26, 2004 (69 FR 68948). In the notice, FDA announced the availability and requested comments on the draft guidance entitled "Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association." The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit written or electronic comments by January 25, 2005.

**ADDRESSES:** Submit written comments 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:** Tim Hansen, Center for Food Safety and Applied Nutrition (HFS-415), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1405, e-mail: [thansen@cfsan.fda.gov](mailto:thansen@cfsan.fda.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of November 26, 2004 (69 FR 68948), FDA published a notice with a 30-day comment period on a draft guidance entitled "Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association."

The agency has received several requests for an extension of the comment period for the notice, ranging from an additional 30 to 90 days. Each request conveyed concern that the current 30-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance document.

FDA has considered the requests for additional time to submit comments and is extending the comment period for the notice and related guidance document for 30 days, until January 25, 2005. The agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying implementation of this important program.

##### **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-28573 Filed 12-27-04; 10:43 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D-0568]

#### **Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices." Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to change the names, revise the identifications, and reclassify the two devices from class III (premarket approval) into class II (special controls). This guidance document describes a means by which the vascular embolization device and the neurovascular embolization device may comply with the requirement of special controls for class II devices. We are also announcing the withdrawal of the 1994 draft guidance document entitled "Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model," dated September 12, 1994.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance on a 3.5" diskette of the guidance entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices" to the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) (HFZ-220), Center for Devices and Radiological Health (CDRH) (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send a self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-442-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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.*

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**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.