

20447, Attn: ACF Reports Clearance Officer. E-mail address: 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.

Dated: December 22, 2004.

Robert Sargis,

Reports Clearance Officer.

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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 In the notice, FDA announced the availability and requested comments on the draft guidance entitled "Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for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.

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.