

an allergenic ingredient due to the nature of the product or the process; (4) products that contain a flavor ingredient that has an allergenic component, but the label of the product only declares the flavor; and (5) products that contain a processing aid that has an allergenic component, but the label does not declare it. FDA believes there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90 percent of all food allergies: Peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat.

FDA is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance is reference material for investigators and other FDA personnel. The guidance does not bind FDA and does not confer any rights, privileges, benefits, or immunities for or on any person(s). An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes, regulations, or both. The guidance will help ensure more effective inspections and further FDA's efforts to prevent potential serious allergic reactions in sensitive individuals resulting from undeclared allergens in food. FDA is making this guidance document effective immediately because public participation prior to its implementation is not appropriate in these circumstances (21 CFR 10.115). Although the guidance document announced in this notice is being implemented immediately, FDA is requesting comments on the guidance. FDA will review all comments received, revise the guidance in response to the comments as appropriate, and publish a notice of availability if the guidance is revised.

## II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written or electronic comments regarding the guide. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Copies of the guidance may also be downloaded to a personal computer

with access to the Internet. The Office of Regulatory Affairs home page includes the guide and may be accessed at <http://www.fda.gov/ora> under "Inspectional References."

Dated: July 27, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01D-0311]

#### **Medical Devices: Draft Guidance on "Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA;" Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA." This draft guidance document will serve as the special control for reclassification of the endolymphatic shunt tube with valve device from class III to class II. The draft guidance document outlines the technical areas to address in order to control the risks associated with the endolymphatic shunt tube with valve and to provide for a timely premarket notification (510(k)) review. This draft guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments on the draft guidance by November 13, 2001.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

James K. Kane, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080.

#### **SUPPLEMENTARY INFORMATION:**

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

FDA is announcing the availability of a draft guidance entitled "Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA." The draft guidance document is the special control guidance for the endolymphatic shunt tube with valve. Elsewhere in this issue of the **Federal Register**, FDA is proposing to reclassify the device from class III to class II when it is intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops of Meniere's Disease. FDA intends that this draft guidance document, if finalized, will serve as the special control for the endolymphatic shunt tube with valve. If finalized, the guidance will supersede the guidance document entitled "Guidance for the Technical Content of a Premarket Approval Application for an Endolymphatic Shunt Tube With Valve" that FDA issued in April 1990.

##### **II. Significance of Guidance**

The draft guidance represents the agency's current thinking on the endolymphatic shunt tube with valve. 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 such approach satisfies the applicable statutes and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

##### **III. Electronic Access**

In order to receive "Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA" via your 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 document number 791 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so 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 the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

#### IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance by November 13, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9

a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 2001.

**Linda S. Kahan,**

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

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### Proposed Project: Evaluation of the Scholarships for Disadvantaged Students (SDS) Program—New

The Scholarships for Disadvantaged Students (SDS) program was established in 1990 to provide financial assistance to health professions and nursing students from disadvantaged backgrounds. A primary tenet of the SDS program is that students who come from disadvantaged backgrounds will be most likely to practice in Medically

Underserved Communities (MUCs) after graduation. In this way, the SDS program is working to alleviate health profession and nursing shortages across the country.

The evaluation of this program will include a mail survey directed at graduates of SDS-participating institutions in the fields of allopathic and osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, pharmacy, nursing, allied health and behavioral and mental health. The survey will be directed at the 1996 graduates of allopathic and osteopathic medicine schools who participated in the SDS program in both 1996 and 2001. The survey will also be directed at the 1999 graduates of dentistry, veterinary medicine, optometry, podiatry, pharmacy, nursing, allied health and behavioral and mental health schools who participated in the SDS program in both 1999 and 2001. The information will identify the place and type of employment for each individual surveyed in order to determine whether or not the individual practiced in a MUC between July 1, 1999, and June 30, 2000. The data collected through this survey will be used to determine whether statistically significant differences exist between the rate at which disadvantaged versus non-disadvantaged individuals and SDS scholarship recipients versus non-recipients practice in MUCs after graduation. These data will also be used to determine whether differences exist in the rates at which individuals in different health professions work in MUCs. The results will be used to formulate programmatic and policy recommendations designed to strengthen the SDS program and increase its effectiveness.

| Type of Survey      | Number of respondents | Number of responses per respondent | Hours per response | Total burden hours |
|---------------------|-----------------------|------------------------------------|--------------------|--------------------|
| Questionnaire ..... | 3,750                 | 1                                  | .25                | 937.5              |

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 9, 2001.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the