

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2008-D-0603]

**Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Tissue Expander; Availability****AGENCY:** Food and Drug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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Tissue Expander." This draft guidance document describes a means by which the tissue expander device type may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to classify this device type into class II (special controls). This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on a final version of the guidance, submit written or electronic comments on the draft guidance by March 23, 2009.

**ADDRESSES:** Submit written requests for single copies of the FDA draft guidance document entitled "Class II Special Controls Guidance Document: Tissue Expander" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Nada Hanafi, Center for Devices and Radiological Health (HFZ-4), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8848

**SUPPLEMENTARY INFORMATION:****I. Background**

A tissue expander is a device intended for temporary (less than 6 months) subdermal implantation to stretch the skin for surgical applications, specifically to develop surgical flaps and additional tissue coverage. It is made of an inflatable silicone elastomer shell filled with Normal Physiological Saline (injection grade). On August 25 and 26, 2005, the General and Plastic Surgery Devices Panel (the Panel) recommended that the tissue expander be classified into class II and that the special control should be a special controls guidance document and labeling. The Panel also considered the types of information the agency should include in a class II special controls guidance document. FDA considered the Panel's recommendations and, elsewhere in this issue of the **Federal Register**, FDA is proposing to classify the tissue expander into class II. If this classification rule is finalized, FDA intends that this guidance document will serve as the special control for this device.

Following the effective date of any final classification rule based on this proposal, any firm submitting a premarket notification (510(k)) for a tissue expander 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.

**II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the tissue expander device type. 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 requirements of the applicable statute and regulations.

**III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Class II Special Controls Guidance Document: Tissue Expander," you may either send an e-mail request to [ds mica@fda.hhs.gov](mailto:ds mica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please

use the document number 1628 to identify the guidance you are requesting.

The Center for Devices and Radiological Health (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>. Guidance documents are also available at <http://www.regulations.gov>.

**IV. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 807, subpart E, have been approved under OMB control no. 0910-0120; the collections of information in 21 CFR part 820 have been approved under OMB control no. 0910-0073; the collections of information in 21 CFR part 812 have been approved under OMB control no. 0910-0078; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control no. 0910-0130; and the collections of information in 21 CFR part 801 have been approved under 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 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.

Please note that on January 15, 2008, the FDA Division of Dockets

Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: December 16, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration

(HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer on (301) 443-1129.

*Comments are invited on:* (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: The Health Professions Student Loan (HPSL) and Nursing Student Loan (NSL) Programs: Forms (OMB No. 0915-0044): Extension**

The HPSL Program provides long-term, low-interest loans to students

attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The NSL Program provides long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma in nursing, and an associate degree, a baccalaureate degree, or a graduate degree in nursing. Participating HPSL and NSL schools are responsible for determining eligibility of applicants, making loans, and collecting monies owed by borrowers on their outstanding loans. The deferment form (HRSA form 519) provides the schools with documentation of a borrower's eligibility for deferment. The Annual Operating Report (AOR-HRSA form 501) provides the Federal Government with information from participating and non-participating schools (schools that are no longer granting loans but are required to report and maintain program records, student records, and repayment records until all student loans are repaid in full and all monies due the Federal Government are returned) relating to HPSL and NSL program operations and financial activities.

The estimate of burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Deferment HRSA-519 .....	2,011	1	2,011	0.166	334
AOR-HRSA-501 .....	907	1	907	4	3,628
<b>Total .....</b>	<b>2,918</b>	<b>.....</b>	<b>2,918</b>	<b>.....</b>	<b>3,962</b>

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 15, 2008.

**Alexandra Huttinger,**

*Director, Division of Policy Review and Coordination.*

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**Proposed Project: Faculty Loan Repayment Program (FLRP) Application (OMB No. 0915-0150)—Extension**

Under the Health Resources and Services Administration (HRSA) Faculty Loan Repayment Program, degree