

Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:**

Anthony D. Watson, 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**

This guidance document describes a means by which surgical suture devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that a manufacturer attempting to establish that its device is substantially equivalent to a predicate class II surgical suture should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

**II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." 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**

In order to receive "Class II Special Controls Guidance Document: Surgical Sutures; 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 the document number (1387) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the 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. 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 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>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

**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 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E were approved under OMB control number 0910-0120.

**V. Comments**

You may submit to Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance by March 19, 2003. You should submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. The guidance document and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 16, 2002.

**Linda S. Kahan,**

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

[FR Doc. 02-31992 Filed 12-18-02; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Pulmonary-Allergy Drugs Advisory Committee; Cancellation**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is canceling the meeting of the Pulmonary-Allergy Drugs Advisory Committee scheduled for December 20, 2002. This meeting was announced in the **Federal Register** of November 13, 2002 (67 FR 68878).

**FOR FURTHER INFORMATION CONTACT:**

Kimberly L. Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX 301-827-6776, or e-mail: [topperk@cder.fda.gov](mailto:topperk@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12545.

Dated: December 16, 2002.

**Linda Arey Skladany,**

*Associate Commissioner for External Relations.*

[FR Doc. 02-32157 Filed 12-17-02; 3:05 pm]

**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 (OMB), 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: Faculty Loan Repayment Program (FLRP)**

*Application (OMB No. 0915-0150)—Revision*

Under the Health Resources and Services Administration Faculty Loan

Repayment Program, disadvantaged graduates from certain health professions may enter into a contract under which HRSA will make payments on eligible educational loans in exchange for a minimum of two years of service as a full-time or part-time faculty

member of an accredited health professions school. Applicants must complete an application and provide current loan balances on all eligible educational loans.

The estimated burden hours for the form is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Applicants .....	94	1	94	1	94

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: December 12, 2002.

**Jane Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 02-31911 Filed 12-18-02; 8:45 am]

**BILLING CODE 4165-15-P**

**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 (OMB), 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: Uncompensated Services Assurance Report (OMB No. 0915-0077)—Revision**

Under the Hill-Burton Act, the Government provides grants and loans for construction or renovation of health care facilities. As a condition of receiving this construction assistance, facilities are required to provide services to persons unable to pay. A condition of receiving this assistance requires facilities to provide assurances periodically that the required level of uncompensated care is being provided, and that certain notification and record keeping procedures are being followed. These requirements are referred to as the uncompensated services assurance.

**Estimate of Information Collection Burden**

Type of requirement and regulatory citation	Number of Responses	Responses per respondent	Total responses	Hours per response	Total hour burden
<b>Disclosure Burden (42 CFR)</b>					
Published Notices (124.504(c)) .....	206	1	206	0.17	35
Individual Notices (124.504(c)) .....	206	1	206	35.5	7,313
Determinations of Eligibility (124.507) .....	206	396	81,576	0.37	30,183
Subtotal Disclosure Burden .....					37,531

Type of requirement and regulatory citation	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
<b>Reporting</b>					
Uncompensated Services Report—HRSA-710 Form (124.509(a)) .....	10	1	10	11.0	110
Application for Compliance Alternatives:					
Public Facilities (124.513) .....	4	1	4	6.0	24
Small Obligation Facilities (124.514(c)) .....	0				
Charitable Facilities (124.516(c)) .....	2	1	2	6.0	12
Annual Certification for Compliance Alternatives:					
Public Facilities (124.509(b)) .....	144	1	144	0.5	72
Charitable Facilities (124.509(b)) .....	28	1	28	0.5	14
Small Obligation Facilities (124.509(c)) .....	1	1	1	0.5	1
Complaint Information (124.511(a)):					
Individuals .....	10	1	10	0.25	3
Facilities .....	10	1	10	0.5	5
Subtotal Reporting Burden .....					241