Dated: May 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 02N–0288]

Medical Devices; Designation of Special Control for Eight Surgical Suture Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend the classification regulations for eight surgical suture devices previously reclassified into class II to specify a special control for those devices. The special control is an FDA guidance document entitled ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA'' that identifies performance, testing, and labeling recommendations for the devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control. FDA is taking these actions on its own initiative because it believes they are necessary to provide reasonable assurance of the safety and effectiveness of surgical suture devices. These actions are being taken under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: This rule is effective July 3, 2003.

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, ext. 164.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115), and the Medical Device User Fee and Modernization Act (MDUFMA) (Public Law 107–250) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance.

SMDA broadened the definition of class II devices to mean those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

The 1976 amendments also broadened the definition of ''device'' in 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified into class III all transitional devices, i.e., those devices previously regulated as new drugs, including surgical sutures.

II. Regulatory History of the Devices

In the **Federal Register** of December 16, 1977 (42 FR 63472), FDA published a notice that identified sutures as class III devices under the transitional provisions of the act. Section 520(l)(2) of the act (21 U.S.C. 360j(l)(2)) provides that the manufacturer or importer of a device classified in class III under the transitional provisions may file a petition for reclassification of the device into class I or class II. Procedures for filing and review of classification petitions are set forth in § 860.136 (21 CFR 860.136).

In accordance with section 520(l)(2) of the act and § 860.136, and after consulting with members of the General and Plastic Surgery Devices Panel, FDA reclassified surgical suture devices from class III to class II as follows:

1. Absorbable poly(glycolide/L-lactide) surgical suture (21 CFR 878.4493), reclassification order (letter) dated September 14, 1989;
2. Stainless steel suture (21 CFR 878.4495), reclassification order (letter) dated July 30, 1986;
3. Absorbable surgical gut suture (21 CFR 878.4830), reclassification order (letter) dated September 19, 1988;
4. Nonabsorbable poly(ethylene terephthalate) surgical suture (21 CFR 878.5000), reclassification order (letter) dated July 5, 1990;
5. Nonabsorbable polypropylene surgical suture (21 CFR 878.5010), reclassification order (letter) dated July 5, 1990;
6. Nonabsorbable polyamide surgical suture (21 CFR 878.5020), reclassification order (letter) dated February 15, 1990;
7. Natural nonabsorbable silk surgical suture (21 CFR 878.5030), reclassification order (letter) dated November 9, 1990; and
8. Nonabsorbable expanded polytetrafluoroethylene surgical suture (21 CFR 878.5035), reclassification order (letter) dated September 9, 1999.

In the **Federal Register** of December 19, 2002 (67 FR 77678), FDA published a proposed rule to designate a special control for eight surgical suture devices already classified into class II. FDA proposed that surgical suture devices would remain in class II, but would be subject to a special control. The proposed rule identified the special control as an FDA guidance document entitled ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' In the same edition of the **Federal Register**, FDA announced the availability of the draft guidance that, when final, was intended to serve as a special control (67 FR 77797). FDA invited interested persons to comment on the proposed rule and on the proposed special control guidance document by March 19, 2003.

III. FDA's Conclusion

FDA received no comments on the proposed rule or on the guidance document proposed as the special control. Therefore, under the SMDA authority, FDA is amending the classification regulations for eight surgical suture devices previously reclassified into class II, to designate a special control for those devices. The special control capable of providing reasonable assurance of safety and effectiveness for these devices is a guidance document entitled ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA'' that identifies performance,

testing, and labeling recommendations for the devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the special control guidance.

Following the effective date of this final rule, any firm submitting a 510(k) premarket notification for a new surgical suture will need to address the recommendations in the special control guidance. However, the firm need only show that its device is as safe and effective as a device that meets guidance recommendations. The firm may use alternative approaches if those approaches address the performance, testing, and labeling issues identified in the guidance.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The special controls guidance document does not impose any new burdens on manufacturers of these devices. FDA has granted 201 substantial equivalence orders from 95 manufacturers of these devices in the last 10 years. The guidance document is based upon the review of the information submitted in these premarket notifications. Based on the review of the premarket notifications, FDA believes that manufacturers presently marketing these devices are in conformance with the guidance document and they will not need to take any further action. The guidance document merely assures that, in the future, devices of these generic types will be at least as safe and effective as the presently marketed devices. These devices are already subject to premarket notification and labeling requirements. The guidance document advises manufacturers on appropriate means of complying with these requirements.

The consensus standards in the guidance were recognized under section 514(c) of the act (21 U.S.C. 360d(c)) for the purpose of demonstrating certain aspects of substantial equivalency. The manufacturer may provide a declaration of conformity to a recognized standard to meet a premarket notification requirement. Ordinarily, this will provide a simplified method of meeting the requirement. The manufacturer may choose to submit other data or information to meet the requirement. The guidance document sets out options that the manufacturer has in this respect.

For the foregoing reasons, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities. In addition, this rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

List of Subjects in 21 CFR Part 878

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Section 878.4493 is amended by revising paragraph (b) to read as follows:

§ 878.4493 Absorbable poly(glycolide/L-lactide) surgical suture.

* * * * *

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

■ 3. Section 878.4495 is amended by revising paragraph (b) to read as follows:

§ 878.4495 Stainless steel suture.

* * * * *

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

■ 4. Section 878.4830 is amended by revising paragraph (b) to read as follows:

§ 878.4830 Absorbable surgical gut suture.

* * * * *

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

■ 5. Section 878.5000 is amended by revising paragraph (b) to read as follows:

§ 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture.

* * * * *

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

■ 6. Section 878.5010 is amended by revising paragraph (b) to read as follows:

§ 878.5010 Nonabsorbable polypropylene surgical suture.

* * * * *

(b) *Classification*. Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

■ 7. Section 878.5020 is amended by revising paragraph (b) to read as follows:

§ 878.5020 Nonabsorbable polyamide surgical suture.

* * * * *

(b) *Classification*. Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

■ 8. Section 878.5030 is amended by revising paragraph (b) to read as follows:

§ 878.5030 Natural nonabsorbable silk surgical suture.

* * * * *

(b) *Classification*. Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

■ 9. Section 878.5035 is amended by revising paragraph (b) to read as follows:

§ 878.5035 Nonabsorbable expanded polytetrafluoroethylene surgical suture.

* * * * *

(b) *Classification*. Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

Dated: May 20, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

28 CFR Part 802

[CSOSA–0003–F]

RIN 3225–AA01

Disclosure of Records

AGENCY: Court Services and Offender Supervision Agency for the District of Columbia.

ACTION: Final rule.

SUMMARY: The Court Services and Offender Supervision Agency for the District of Columbia (''CSOSA'' or ''Agency'') is adopting regulations on the disclosure of CSOSA or the District of Columbia Pretrial Services Agency (''PSA'' or ''Agency'') records. These regulations include procedures for processing requests for disclosure under the Freedom of Information Act, under the Privacy Act, and for the production of records in response to a subpoena or other legal demand for testimony. The regulations also identify Privacy Act systems of records exemptions for both CSOSA and PSA. These regulations are necessary in order to ensure that the public has appropriate access to information maintained by the Agency and that adequate safeguards are in place to protect the privacy rights of individuals.

EFFECTIVE DATE: July 3, 2003.

ADDRESSES: Office of the General Counsel, CSOSA, Room 1253, 633 Indiana Avenue, NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Roy Nanovic, Records Manager (telephone: (202) 220–5359; e-mail: *roy.nanovic@csosa.gov*).

SUPPLEMENTARY INFORMATION: The Court Services and Offender Supervision Agency for the District of Columbia (''CSOSA'' or ''Agency'') is adopting regulations (28 CFR part 802) on the disclosure of records maintained by CSOSA or the District of Columbia Pretrial Services Agency (''PSA'' or ''Agency''). CSOSA published a proposed rule on this subject in the **Federal Register** on March 15, 2002 (67 FR 11804). As noted in the proposed rule, PSA is an independent entity within CSOSA.

Summary of Regulatory Provisions

Subpart A of the proposed regulations provides a general introduction. Subpart B covers procedures for Freedom of Information Act (FOIA) requests; subpart C covers procedures for Privacy Act requests; subpart D covers disclosures in response to subpoenas or other legal demands; and subpart E covers exemptions to CSOSA and PSA Privacy Act systems of records.

Freedom of Information Act Requests

The general guidelines for disclosure (§ 802.3) under the FOIA note that a record must be in the possession and control of the agency at the time of the request to be considered subject to release under the regulations. There is no obligation to create, compile, or obtain a record to satisfy a FOIA request. Hard copy of electronic records which are subject to FOIA, but which are available to the public through an established distribution system, the **Federal Register**, or the Internet at CSOSA's Web site (*http://www.csosa.gov*), normally do not need to be processed under the FOIA. CSOSA will process such requests under the FOIA only if the requester insists on such processing.

Definitions for certain terms used in the subpart are contained in § 802.4. The procedures for submitting and processing FOIA requests are contained in § 802.5. Section 802.6 explains how CSOSA handles requests for documents which relate to or were created by another agency.

Section 802.7 covers the denial of a request. This section also explains how the requester may appeal the denial. Section 802.8 explains how to request expedited processing. Section 802.9 covers procedures for the disclosure of business information which may have been provided to the Agency. The business submitter (any entity which provided the business information to the Agency and which has a proprietary interest in the information) will receive notice of the FOIA request and have an opportunity to object to disclosure. Section 802.10 contains the fee schedule for FOIA requests.

Privacy Act Requests

The regulations in subpart C are intended to let you know how you can determine whether CSOSA or PSA maintains records about you, how you can obtain access to your records, and how to have your records corrected or amended.

Definitions for certain terms used in the subpart are contained in § 802.12. Section 802.13 explains how to verify your identity when making a request for your own records and how to document that you have consent when you make a request for information concerning another individual. The procedures for submitting and processing requests for access to records are contained in