ATTACHMENT 1—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING JUNE 26, 2003—Continued

| | Medical specialty | Device type | 21 CFR section | Class | Product code | Risk* | Critical/semi-critical/noncritical | Premarket exempt |
|---|---|---|---|---|---|---|---|---|
| 210 | Surgery | Ac-Powered Motor | 878.4820 | I | GEY | 2 | C | Y |
| 211 | Surgery | Bit | 878.4820 | I | GFG | 1 | C | Y |
| 212 | Surgery | Bur | 878.4820 | I | GFF, GEY | 1 | C | Y |
| 213 | Surgery | Cardiovascular Surgical Saw Blade | 878.4820 | I | DWH | 1 | C | Y |
| 214 | Surgery | Chisel (Osteotome) | 878.4820 | I | KDG | 1 | C | Y |
| 215 | Surgery | Dermatome | 878.4820 | I | GFD | 1 | C | Y |
| 216 | Surgery | Electrically Powered Saw | 878.4820 | I | DWI | 2 | C | Y |
| 217 | Surgery | Pneumatic Powered Motor | 878.4820 | I | GET | 2 | C | Y |
| 218 | Surgery | Pneumatically Powered Saw | 878.4820 | I | KFK | 2 | C | Y |
| 219 | Surgery | Powered Saw and Accessories | 878.4820 | I | HAB | 2 | C | Y |
| 220 | Surgery | Saw Blade | 878.4820 | I | GFA | 1 | C | Y |
| 221 | Surgery | Nonpneumatic Tourniquet | 878.5900 | I | GAX | 1 | N | Y |
| 222 | Surgery | Pneumatic Tourniquet | 878.5910 | I | KCY | 1 | N | Y |
| 223 | Surgery | Endoscopic Staplers | 888.4540 | I | HXJ | 2 | C | Y |
| 224 | Surgery | Trocar | 876.1500<br>870.1390 | II | GCJ, DRC | 3 | C | N |
| 225 | Surgery | Surgical Cutting Accessories | 878.4800<br>874.4420 | I | GDZ, GDX, GES, KBQ, KAS | 2 | C | Y |
| 226 | Surgery | Electrosurgical Electrodes/Handles/Pencils | 876.4300<br>878.4400 | II | HAM, GEI, FAS | 2 | C | N |
| 227 | Surgery | Scissor Tips | 878.4800<br>884.4520<br>874.4420 | I | LRW, HDK, HDJ, JZB, KBD | 2 | C | Y |
| 228 | Surgery | Laser Fiber Delivery Systems | 878.4810<br>874.4500<br>886.4390<br>884.4550<br>886.4690 | II | GEX, EWG, LLW, HQF, HHR, HQB | 1 | C | N |

[1] N means no.
[2] Y means yes.
† Indicates a change since last publication.

Dated: June 20, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–16109 Filed 6–25–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003D–0236]**

### Draft ''Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis;'' Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis'' dated June 2003. The draft guidance document provides recommendations for testing donors of blood and blood components for syphilis, and for recommended actions based on those test results. The

recommendations described in the document are for blood establishments that use either nontreponemal-based or treponemal-based screening assays to test donors for serological evidence of syphilis infection. These recommendations, when finalized, will replace previous recommendations contained in a Memorandum to Registered Blood Establishments dated December 12, 1991.

**DATES:** Submit written or electronic comments on the draft guidance by September 24, 2003, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the 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.fda.gov/dockets/ecomments.

**FOR FURTHER INFORMATION CONTACT:** Joseph L. Okrasinski, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis'' dated June 2003. The draft guidance document provides specific recommendations for donor testing and management, and product disposition when using screening tests for syphilis. The recommendations are for blood establishments that use either nontreponemal-based or treponemal-based screening assays for serological evidence of syphilis infection. These recommendations, when finalized, will replace the previous recommendations contained in a Memorandum to Registered Blood Establishments dated December 12, 1991.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

### II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: June 18, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF HOMELAND SECURITY

## Bureau of Customs and Border Protection

## Agency Information Collection Activities: Comment Request

*Action:* 60-day notice of information collection under review; Report of Compliant; Form I–847.

The Department of Homeland Security (DHS), Bureau of Immigration and Customs Enforcement has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until August 25, 2003.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Report of Complaint.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–847. Border Patrol Division, Bureau of Customs and Border Protection.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form is used to establish a record of complaint and to initiate an investigation of misconduct by an officer of the DHS.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 250 responses at 15 minutes (.25 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 63 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or