## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. 01M–0309, 01M–0342, 01M–0329, 01M–0381, 01M–0371, 01M–0412, 01M–0305, 01M–0337, 01M–0296, 01M–0310, 01M–0306, 01M–0307, 01M–0360, 01M–0380, 01M–0373, 01M–0392, 01M–0413, 01M–0414, 01M–0439]**

### Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Dockets Management Branch.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

**FOR FURTHER INFORMATION CONTACT:** Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Instead, revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on the Internet at http://www.fda.gov; by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch; and by publishing in the **Federal Register** after each quarter a list of available safety and effectiveness summaries of approved PMAs and denials announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2001, through September 30, 2001, in accordance with the procedure explained previously. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE JULY 1, 2001, THROUGH SEPTEMBER 30, 2001

| PMA No./Docket No. | Applicant | Trade Name | Approval Date |
|---|---|---|---|
| P970056/01M–0309 | Bausch & Lomb Surgical | KERACOR 116 Ophthalmic Excimer Laser System | September 28, 1999 |
| P980044/01M–0342 | Quintiles, Inc. | SUPARTZ Dispo | January 24, 2001 |
| P000016/01M–0329 | GE Medical Systems Information Technologies | Corometrics Model 120 F-Series Maternal/Fetal Monitor with Integrated Fetal Oxygen Saturation Monitoring, Corometrics Fetal Patient Module, and the Nellcor OXIFIRST FS14 Sensor | February 9, 2001 |
| P000007/01M–0381 | Edwards Lifesciences, LLC | EDWARDS PRIMA Plus Bioprosthesis Model 2500P | February 27, 2001 |
| P990026/01M–0371 | Cygnus, Inc. | GLUCOWATCH Automatic Glucose Biographer | March 22, 2001 |
| P000032/01M–0412 | CryoGen, Inc. | HEROPTION UTERINE CRYOBLATION THERAPY System | April 20, 2001 |
| P930016(S12)/01M–0305 | VISX, Inc. | STAR Excimer Laser System Models S2 and S3 | April 27, 2001 |
| P000005/01M–0337 | MediTeam AB | CARISOLV Non-Invasive Dental Caries Removal System | June 27, 2001 |
| P000043/01M–0296 | TherMatrx, Inc. | TMx2000 BPH Thermotherapy System | June 29, 2001 |
| P000021/01M–0310 | Dade Behring, Inc. | DIMENSION RxL PSA Reagent Cartridge | July 5, 2001 |
| P000041/01M–0306 | Deus Technologies, LLC | RAPIDSCREEN RS–2000 | July 12, 2001 |
| P000026/01M–0307 | STAAR Surgical Co. | AQUAFLOW Collegen Glaucoma Drainage Device, Model CGDD–20 | July 12, 2001 |
| P000055/01M–0360 | Diagnostic Medical Systems | UBIS 5000 | July 17, 2001 |
| P830039(S7)/01M–0380 | Medical CV, Inc. | OMNICARBON Cardiac Valve Prosthesis | July 26, 2001 |
| P010015/01M–0373 | Medtronic, Inc. | INSYNC Biventricular Pacing System including INSYNC Model 8040 Pulse Generator, ATTAIN LV Model 2187 and ATTAIN CS Model 2188 Leads | August 28, 2001 |
| H010001/01M–0392 | Avanta Orthopaedics, Inc. | Avanta Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis | August 28, 2001 |
| P010016/01M–0413 | Ortec International, Inc. | ORCEL (Bilayered Cellular Matrix) | August 31, 2001 |

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE JULY 1, 2001, THROUGH SEPTEMBER 30, 2001—Continued

| PMA No./Docket No. | Applicant | Trade Name | Approval Date |
|---|---|---|---|
| P010023/01M–0414 | SOUNDTEC, Inc. | SOUNDTEC Direct System | September 7, 2001 |
| P000029/01M–0439 | Q-Med AB | DEFLUX Injectable Gel | September 24, 2001 |

### II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/cdrh/pmapage.html.

Dated: December 31, 2001.

**Linda S. Kahan,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01D–0545]**

### ''Guidance for Industry: Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax;'' Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax'' dated October 2001. The guidance document provides the current recommendations for assessment of donor suitability and product safety for donors potentially exposed to anthrax. The guidance document applies to Whole Blood, blood components (including recovered plasma) and Source Plasma collections intended for use in transfusion or for further manufacturing into injectable products.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this 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 document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the document 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.

**FOR FURTHER INFORMATION CONTACT:** Valerie A. Butler, 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 document entitled ''Guidance for Industry: Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax'' dated October 2001. The guidance document provides the current recommendations for assessment of donor suitability and product safety for donors potentially exposed to *Bacillus anthracis*, the agent of anthrax. The guidance document applies to Whole Blood, blood components (including recovered plasma) and Source Plasma collections intended for use in transfusion or for further manufacturing into injectable products. FDA developed the recommendations in the guidance document in consultation with other Public Health Service agencies and with the Blood Safety Committee of the Department of Health and Human Services. Recommendations addressed in the guidance include: Donor deferral, product quarantine and retrieval, and notification of prior transfusion recipients.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on recommendations for assessment of donor suitability and product safety for donors potentially exposed to anthrax. 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 agency is soliciting public comment, but is implementing this guidance document immediately because of public health concerns. Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document 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

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

Dated: December 26, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97D–0530]**

### FDA Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 006

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