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 PMA's for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from July 1, 1999, through September 30, 1999. 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 PMA'S MADE AVAILABLE JULY 1, 1999, THROUGH SEPTEMBER 30, 1999

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P930016(S5)/99M–0293	Visx, Inc.	Visx Excimer Laser System Models "B"	January 29, 1998
P970032/99M–2168	BIEX, Inc.	SalEst™ System	April 29, 1998
P950015/99M–2672	PLC Medical Systems, Inc.	The Heart Laser™ CO2 Laser System for Transmyocardial Revascularization	August 20, 1998
P980012/99M–2605	Baxter Healthcare Corp.	Novacor® LVAS	September 29, 1998
P980035/99M–2671	Medtronic, Inc.	Medtronic Kappa™ 700/600 Series Pulse Generators and Model 9953 Software	January 29, 1999
P970029/99M–2238	Eclipse Surgical Technologies, Inc.	TMR Holmium Laser System	February 11, 1999
P980031/99M–1167	KeraVision, Inc.	ICRS (Intrastromal Corneal Ring Segments)	April 9, 1999
P970004(S4)/99M–1306	Medtronic, Inc.	Medtronic Interstim Contenence Control System	April 15, 1999
P970033/99M–1073	TransScan Medical, Inc.	T–Scan 2000	April 16, 1999
P980046/99M–2143	Home Access Health Corp.	Hepatitis C Check℠/Express	April 28, 1999
D970003/99M–2606	Guidant Corp.	Guidant PULSAR™/PULSAR Max™	June 3, 1999
P980022/99M–2169	Minimed Technologies, Inc.	Continuous Glucose Monitoring System	June 15, 1999
P970018/99M–2144	AutoCyte, Inc.	AutoCyte Prep System	June 17, 1999
P950021(S1)/99M–2748	Bayer Corp.	Bayer Immuno 1™ PSA Assay	June 25, 1999
P980052/99M–2551	TMJ Concepts	TMJ Concepts Patient–Fitted TMJ Reconstruction Prosthesis	July 2, 1999
H990004/99M–4134	Nitinol Medical Technologies, Inc.	CardioSEAL Septal Occlusion System	September 8, 1999

Dated: November 24, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–31699 Filed 12–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4910]

Draft Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3.'' This draft guidance document is intended to assist facilities and their personnel to implement the Mammography Quality Standards Act of 1992 (the MQSA).

DATES: Written comments concerning this draft guidance must be received by March 8, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5′ diskette of the draft guidance document entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document # 3'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

The MQSA was passed on October 27, 1992, to establish national quality standards for mammography. After October 1, 1994, the MQSA required all mammography facilities, except facilities of the U.S. Department of Veterans Affairs, to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated to FDA by the Secretary to FDA. On October 28, 1997, FDA published the MQSA final regulations in the **Federal Register**. The final regulations became effective April 28, 1999, and replaced the interim regulations (58 FR 67558 and 58 FR 67565). Development of this draft

guidance document began in March 1999.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the final regulations implementing the MQSA. The draft guidance is not final nor is it in effect at this time. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1496) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft 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 with access to the Internet. Updated on a regular basis, the CDRH Home Page includes ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document # 3,'' 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. ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document # 3'' will be available at http://www.fda.gov/cdrh/mammography.

IV. Comments

Interested persons may, on or before March 8, 2000, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 24, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–31777 Filed 12–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4809]

Draft Guidance for Industry on Applications Covered by Section 505(b)(2); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Applications Covered by Section 505(b)(2).'' A section 505(b)(2) application is a new drug application (NDA) for which one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This draft guidance also provides information on procedures for submitting an application for approval of a change from an approved drug.

DATES: Written comments on the draft guidance may be submitted by February 7, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Khyati N. Roberts, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Applications Covered by Section 505(b)(2).'' Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) describes three types of NDA's: (1) An application that contains full reports of investigations of safety and effectiveness (section 505(b)(1) of the act); (2) an application that contains full reports of investigations of safety and effectiveness but where at least one of those reports required for approval was not conducted by or for the applicant or for which the applicant has not obtained a right of reference (section 505(b)(2) of the act); or (3) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, as a previously approved product (section 505(j) of the act).

Section 505(b)(2) of the act was added to the act by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman amendments). It explicitly allows FDA to rely, for approval of an NDA, on data not developed by the applicant. Section 505(b)(2) and (j) of the act replaced FDA's paper NDA policy, which had permitted an applicant to rely on studies published in the scientific literature to demonstrate the safety and effectiveness of duplicates of certain post-1962 pioneer drug products (46 FR 27396, May 19, 1981). Enactment of the generic drug approval provision of the Hatch-Waxman amendments ended the need for approvals of duplicate drugs through the paper NDA process. Specifically, section 505(j) of the act allows for approval of duplicates of approved NDA's on the basis of chemistry and bioequivalence data. Section 505(b)(2) of the act allows for approval of applications other than those for duplicate products.