device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the Internet on the CDRH home page at http://www.fda.gov/cdrh or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. Petition

FDA received the following petition requesting an exemption from premarket notification for class II devices: Baxter Healthcare, Pharmacy Compounding Systems Classified within the *Intravascular administration set*, 21 CFR 880.5440.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this petition by January 16, 2001. 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 petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 5, 2000.

Linda S. Kahan,

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

[FR Doc. 00–31961 Filed 12–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00M–1391, 00M–1536, 00M–1447, 00M–1522, 00M–0809, 00M–1517, 00M–1451, 00M–1448, 00M–1507, 00M–1389, 00M–1388, 00M–1508, 00M–1390, 00M–1386, 00M–1387, 00M–1414, 00M–1415, 00M–1416, 00M–1495, 00M–1437, 00M–1475, 00M–1483, 00M–1515, 00M–1524, 00M–1523]

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 (PMA's) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMA's through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Submit a written request 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 summary 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 FDA's home page at http://www.fda.gov on the Internet; 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 PMA's 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 PMA's for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from July 1, 2000, through September 30, 2000. 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, 2000, THROUGH SEPTEMBER 30, 2000

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P930016(S7)/00M–1391	VISX, Inc.	VISX STAR S2 Excimer Laser System	November 2, 1998
P920030(S2)/00M–1536	Chiron Corp.	CIBA Corning ACS PSA Immunoassay	December 8, 1998
P910065(S1)/00M–1523	Tosoh Medics, Inc.	AIA–PACK PA	September 10, 1999
P990010/00M–1447	CRS Clinical Research, Inc.	VISX Inc. Excimer Laser System Model C ''STAR''	November 19, 1999
P940035(S2)/00M–1522	Matritech Inc.	Matritech NMP22® Test Kit	January 18, 2000
P990023/00M–0809	Alcon Laboratories	Cellugel® Ophthalmic Viscosurgical Device	February 24, 2000
P990054/00M–1517	Cardiac Pathways Corp.	Chilli® Cooled Ablation System	March 17, 2000
H990014/00M–1451	Medtronic Inc.	Enterra™ Therapy System (formerly named Gastric Electrical Stimulation (GES) System)	March 31, 2000
P990053/00M–1448	Nellcor Puritan Bennett	OxiFirst® Fetal Oxygen Saturation Monitoring System	May 12, 2000
P990028/00M–1507	Focal, Inc.	Focal Seal-L Synthetic Absorbable Sealant	May 26, 2000
P980050/00M–1389	Medtronic Inc.	Medtronic® Jewel® AF 7250 Dual Chamber Implantable Cardioverter Defibrillator	June 14, 2000
P990025/00M–1388	Biosense Webster, Inc.	NAVI–STAR Diagnostic/Ablation Deflectable Tip Catheter	June 15, 2000
P950032(S16)/00M–1508	Organogenesis, Inc.	Apligraf (Graftskin)	June 20, 2000
P99037/00M–1390	Vascular Solutions, Inc.	Vascular Solutions Duett Sealing Device	June 22, 2000
P990078/00M–1386	Sunrise Technologies	Hyperion LTK System	June 30, 2000
P990021/00M–1387	QLT Photo Therapeutics, Inc.	Diomed 630 PDT Laser, Model T2USA	June 30, 2000
P990018/00M–1414	Menicon USA, Inc.	Menicon™ Z Rigid Gas Permeable Contact Lens	July 11, 2000
P000006/00M–1415	Mentor Corp.	Alpha 1 Inflatable Penile Prosthesis	July 14, 2000
P990064/00M–1416	Medtronic Inc.	Mosaic® Porcine Bioprosthesic Heart Valve	July 14, 2000
P990034/00M–1495	Medtronic Inc.	Medtronic® IsoMed® Constant Flow Infusion System	July 21, 2000
P990039/00M–1437	Metra Biosystems, Inc.	QUS–2™ Calcaneal Ultrasonometer	August 1, 2000
P990072/00M–1475	Westcon Contact Lens Co., Inc.	W–55 (Methafilcon A) and Horizon 55 Soft Extended Wear Contact Lenses	August 22, 2000
P860057(S11)/00M–1483	Edwards Lifesciences, LLC	Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis	August 28, 2000
P970042/00M–1515	Medstone International, Inc.	Medstone STS™ Lithotripter	September 5, 2000
P990055/00M–1524	Bayer Corp.	Bayer Immuno 1™ Complexed PSA Assay	September 8, 2000

II. Electronic Access

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

Dated: December 5, 2000.

Linda S. Kahan,

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

[FR Doc. 00–31960 Filed 12–14–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1392]

Draft Guidance for Industry on Botanical Drug Products; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the draft guidance for industry entitled ''Botanical Drug Products'' until March 15, 2001. This draft guidance explains the circumstances under which FDA approval of a new drug application (NDA) is required for marketing of a botanical drug product and when such a product may be marketed under an over-the-counter (OTC) drug monograph. It also provides guidance to researchers and manufacturers on conducting initial and expanded clinical investigations of botanical drug products. FDA is taking this action in response to a request for an extension.

DATES: Submit written comments on the draft guidance by March 15, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research