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]

BILLING CODE 4160–01–F

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

(CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5918. Send two self-addressed adhesive labels 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. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Yuan-Yuan Chiu, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5918.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 11, 2000 (65 FR 49247), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Botanical Drug Products.'' The draft guidance is intended to encourage the clinical study and submission for marketing approval of botanical drug products. The guidance explains the circumstances under which FDA approval of an NDA is required for marketing a botanical drug and when such a drug may be marketed under an OTC drug monograph. The draft guidance also provides scientific and regulatory guidance to sponsors about conducting initial and expanded clinical investigations of botanical drugs, including those botanical products currently lawfully marketed as foods and dietary supplements in the United States. In particular, the guidance provides information on how the agency will interpret and apply to botanical drugs certain provisions of existing regulations on the submission of investigational new drug applications (IND's) (21 CFR part 312). Interested persons were given until October 10, 2000, to submit written comments on the draft guidance.

FDA received a letter, dated September 15, 2000, from Diane C. McEnroe of the firm of Sidley & Austin, in behalf of a research-based company based in Asia, requesting that the agency extend the comment period on the draft guidance by 90 days.

The draft guidance introduces several new and highly technical issues. Therefore, the agency has decided to reopen the comment period on the draft guidance until March 15, 2001, to allow the public more time to review and comment on its contents.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document by March 15, 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 draft 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: December 7, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–31948 Filed 12–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4565–N–32]

Management Review Report for Subsidized Multifamily Housing Programs

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* February 13, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, L'Enfant Building, room 8202, Washington, DC 20410, telephone (202) 708–5221 (this is not a toll-free number) for copies of the proposed forms and other available information.

FOR FURTHER INFORMATION CONTACT: Beverly J. Miller, Director, Policy and Participation Standards Division, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410, telephone number (202) 708–1320 (this is not a toll-free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection 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 agency's estimate of the burden of the proposed collection of information; (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 the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Management Review Report for Subsidized Multifamily Housing Programs.

OMB Control Number, if applicable: 2502–0259.

Description of the need for the information and proposed use: Owners are required to submit Management Review Reports when the owner changes management agents, when a project has been determined to be an unacceptable risk, or the owner and agent negotiate a new management fee and/or management agreement, or the agent makes major changes in its organization structure.

Agency form numbers, if applicable: HUD–9838.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The number of respondents of HUD staff and Contract Administrators is 900; the frequency of responses is 1; estimated time to prepare collection is 8 hours per response, and the total annual burden hours are 7,200.

Status of the proposed information collection: Revision of currently approved collection.

Authority: The Paperwork Reduction Act of 1955, 44 U.S.C., Chapter 35, as amended.

Dated: December 11, 2000.

William C. Apgar,

Assistant Secretary for Housing—FHA.

[FR Doc. 00–31985 Filed 12–14–00; 8:45 am]

BILLING CODE 4210–27–M