devices that have serious problems and to ensure that dangerous and defective devices are removed from the market, assuring that FDA has current and complete information regarding these corrections and removals and whether recall action is adequate. Failure to collect this information prevents FDA from receiving timely information about devices that may have a serious effect on the health of the users of the devices.

Respondents to this information collection are businesses or other for-profit manufacturers or importers of medical devices who must remove or correct medical devices that cause public health risk to the general public.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	880	1	880	10	8,800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
806.20(a)	440	1	440	10	4,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The following is an explanation of the burden estimate:

Reporting Burden

FDA estimates that it would take 10 staff hours to prepare and assemble a written report. For the estimated 880 reports, FDA estimates that respondents will spend 8,800 hours to prepare, assemble, and send the reports.

Recordkeeping Burden

FDA estimates that it would take 10 staff hours to prepare a written record. For the estimated 440 records, the total recordkeeping burden is estimated at 4,400 hours per recordkeeper.

Dated: June 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–16989 Filed 7–5–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00M–1592, 01M–0072, 01M–0043, 00M–0014, 00M–0012, 00M–0011, 01M–0042, 00M–0055, 01M–0039, 00M–0015, 01M–0041, 00M–1683, 00M–0013, 00M–1684, 01M–0038, 01M–0062, 01M–0149, 01M–0201]

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 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 Intranet home page 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 in accordance with the procedure explained previously from January 1, 2001, through March 31, 2001. 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 JANUARY 1, 2001, THROUGH MARCH 31, 2001

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P970043/00M–1592	Autonomous Technologies Corp.	LADARVision® Excimer Laser System	November 2, 1998
P970025/01M–0072	DiaSorin, Inc.	PRO–TRAC II™ Tacrolimus ELISA Kit	April 27, 1999
P970049/01M–0043	Laser Institute of the Rockies	Dishler Excimer Laser System	December 16, 1999
P970053(S2)/00M–0014	Nidek Technologies, Inc.	EC 5000 Excimer Laser System	April 14, 2000
P990074/00M–0012	McGhan Medical Corp.	RTV Saline-Filled Breast Implants	May 10, 2000
P990075/00M–0011	Mentor Corp.	Saline-Filled and Spectrum® Mammary Prostheses.	May 10, 2000
P000009/01M–0042	Biotronik, Inc.	Phylax AV Implantable Cardioveter Defibrillator with Program Software.	September 29, 2000
P000011/00M–0055	Biocompatibilities Cardiovascular, Inc.	Biodiv Ysio™ AS PC Coated Stent and Delivery System.	September 29, 2000
P000022/01M–0039	Medtronic AVE, Inc.	AVE BeStent™ 2 with Discrete Technology™ Coronary Stent Delivery System.	October 16, 2000
P930016(S10)/00M–0015	VISX, Inc.	STAR S2 and S3 Excimer Laser System.	October 18, 2000
P910023(S47)/01M–0041	St. Jude Medical, Inc.	Photon™ DR Implantable Cardioverter Defibrillator (ICD).	October 27, 2000
P000027/00M–1683	Roche Diagnostics Corp.	Elecsys Free Immunoassay Calset/ Calcheck.	December 12, 2000
P970013/00M–0013	St. Jude Medical, Inc.	Microny™ SR+ Model 2425T	December 21, 2000
P980020/00M–1684	Q Care International, LLC	Q 103 Needle Management Systems	December 21, 2000
P950021(S2)/01M–0038	Bayer Corp.	ACS: 180 and Advia Centaur PSA Assays.	December 22, 2000
H000001/01M–0062	JOMED AB	JOMED JOSTENT® Coronary Stent Graft.	January 10, 2001
P990085/01M–0149	VISTAKON (Division of Johnson & Johnson Vision Care, Inc.).	VISTAKON Soft Contact Lenses for Extended Wear.	February 16, 2001
H990013/01M–0201	Ortec International, Inc.	Composite Cultured Skin (CCS)	February 21, 2001

II. Electronic Access

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

Dated: June 21, 2001.

Linda S. Kahan,

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

[FR Doc. 01–16918 Filed 7–5–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–00–4001]

Memorandum of Understanding Between the Maryland Department of Health and Mental Hygiene and the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Maryland Department of Health and Mental Hygiene and the Food and Drug Administration. The purpose is to set forth conditions for the utilization of Maryland Medicaid data for the study entitled ''Compliance with Liver Testing Labeling Guidelines by Health Care Providers.''

DATES: The agreement became effective December 12, 2000.

FOR FURTHER INFORMATION CONTACT: Katrina S. Garry, Center for Drug Evaluation and Research (HFD–400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3192.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: June 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

BILLING CODE 4160–01–C