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

225-00-4001

MEMORANDUM OF UNDERSTANDING BETWEEN THE MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE AND FOOD AND DRUG ADMINISTRATION

This Memorandum of Understanding ("MOU") is made by and between the Maryland Department of Health and Mental Hygiene, Office of the Deputy Secretary for Health Care Policy Financing (hereinafter called "the Department") and Food and Drug Administration, a federal governmental entity, (hereinafter called "FDA"). The term of this Memorandum of Understanding will commence August 15, 2000 and shall terminate December 31, 2001.

SECTION ONE: PURPOSE

This agreement sets forth conditions for the utilization of Maryland Medicaid data for the study entitled "Compliance with Liver Testing Labeling Guidelines by Heath Care Providers".

SECTION TWO: NATURE AND USE OF THE DATA

The data subject to this MOU will be derived from the Maryland Medicaid claims database and eligibility files. The identifying information (e.g., all Medicaid identification numbers) necessary to link one person's medical information across claims databases and over time will be removed from the file prior to the data's release from the Department, and where necessary replaced with non-identifiable data (e.g., change birth date to age in years, dummy identification numbers). Data collected for each eligible patient would include the data and type of each liver function test (determined from service claims), basic demographic characteristics, type of eligibility, whether or not they are in a skilled nursing facility, and the type of health care provider treating the patient. A profile for liver testing practices among different medical specialties stratified by patient age, sex, underlying medical conditions, and practice setting will be described.

SECTION THREE: BUDGET AND BILLING

There is no cost to the Department and the FDA associated with this Memorandum of Understanding. If there are any costs, each party will be responsible for their own costs.

SECTION FOUR: CONDITIONS FOR UTILIZATION OF MARYLAND MEDICAID DATA

The specific conditions for utilization of Maryland Medicaid data agreed to under this MOU are set forth as follows:

The FDA agrees:

1. Not to utilize Maryland Medicaid data without prior written approval from the Department and, where applicable, from the Department Institutional Review Board, and will not use the data to pursue new hypotheses generated during the course of the study, without prior review and approval from the Department and the Department Institutional Review Board;

2. To provide to the Department an updated listing of employees with data access with a statement certifying that only those individuals will have access to the data.

3. To establish appropriate administrative, technical, procedural, and physical safeguards to protect the data and to prevent unauthorized access to it;

4. To use the data for the stated purpose only, and not for any other purpose without prior written approval of the Department;

5. That it may not give Maryland Medicaid data to any other party without prior written approval from the Department, except as required by federal law (e.g., Freedom of Information Act, Federal court order, or request of Congress);

6. Absent express written authorization from the Department, to make no attempt to link records included in the file(s) to any other individual-specific source of information;

7. To treat any non-confidential data with small cell sizes that could reasonably be expected to permit deduction of a beneficiary's identity like confidential data and not publish or release such data, except as required by Federal law (e.g., Freedom of Information Act, Federal court order, or request of Congress);

8. To provide the Department with a copy of any report, written or oral presentation, written analysis, study, article or similar document which makes reference to the data, at least fourteen days prior to release to any other parties, unless otherwise required by Federal law (e.g., congressional subpoena or Federal court order).

9. To acknowledge the contribution of the Department in presentations and publications;

10. To submit quarterly reports to the Department which shall include:
    - the status of the study project;
    - a description of any significant change in the study protocol;
    - a listing of any changes in the staff utilizing the data;
    - a description of any known or anticipated changes in the study design or procedures that may affect the interests and rights of Medicaid recipients;
    - a copy of the IRB approval of the modification, or proposed change in the study design or procedures;
    - copies of any new analyses, reports or presentations; and
    - a statement of any significant new finding.

11. To present periodic updates of the findings and the status of the study to the Medicaid Directors; and

12. Upon completion of the study or termination of this agreement, to destroy all files containing Maryland Medicaid data (including but not limited to systems files, personal computer files and mainframe storage files), unless prior written approval for data retention has been obtained from the Department or otherwise required by Federal law.

SECTION FIVE: DUTIES OF THE DEPARTMENT

1. The Department will remove all personal identifiers from the Medicaid data prior to the data's release from the Department; and

2. The Department will assist the FDA in completing annual review by the Department Institutional Review Board, as necessary.

SECTION SIX: TERMINATION

Either party may terminate this MOU upon thirty (30) days written notice to the other party. Upon termination by either party, the FDA will destroy all Maryland Medicaid data files (in accordance with Section Four, paragraph 12, above) and all utilization of the Maryland Medicaid information will cease.

The Department may immediately suspend or terminate approval of utilization of Medicaid data for research that is not being conducted in accordance with the IRB's of Medicaid's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reason for the action and shall be reported promptly to the investigator and appropriate institutional officials.

SECTION SEVEN: MONITORS

The MOU Monitor for the Department shall be:

Ms. Frances Cipriotti
Research Data Coordinator
Planning, Development and Finance Administration
201 West Preston Street, Room 225
Baltimore, Maryland 21201
410-767-5945: 410-333-7505 fax

The Department MOU Monitor is the primary point of contact within the Department for matters relating to this MOU. The FDA Monitor shall contact this person if the FDA is unable to fulfill any of the requirements of, or has any questions regarding, the interpretation of the provisions of this MOU.

The MOU Monitor for the FDA shall be:

Ms. Janet Woodcock, M.D.
Director
FDA/CDER
1451 Rockville Pike, Room 6027, HFD-1
Rockville, Maryland 20852
301-594-5400: 301-594-6197 fax

The FDA MOU Monitor is the primary point of contact for matters relating to this MOU. The Department MOU Monitor shall contact this person immediately if the Department is unable to fulfill any of the requirements of, or has questions regarding, the interpretation of the provisions of this MOU.

SECTION EIGHT: MISCELLANEOUS

This MOU and any documents incorporated into the MOU may be amended only by a written modification signed by the authorized officials of both parties.

The remainder of this page is blank.

In acknowledgement of the foregoing description of the terms and conditions for the utilization of Maryland Medicaid and the requirements of this MOU these authorized signatories of the Department and the FDA do hereby attest to their acceptance of the terms and conditions of this Memorandum of Understanding.

FOR THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE

GEORGES C. BENJAMIN, M.D.
SECRETARY

OR

ALICE BURTON
(signature)

Alice Burton,
Director, Office of the Deputy Secretary for Health Care Policy Financing
12/4/00
Date of Signing

APPROVED AS TO THE FORM AND LEGAL SUFFICIENCY

This 12th Day of December 2000

L. Chris Cashiola
Assistant Attorney General
Office of the Attorney General

FOR THE FOOD AND DRUG ADMINISTRATION

11/21/00
Date

Janet Woodcock, MD
Director
Center for Drug Evaluation and Research
Food and Drug Administration, Rockville

Acknowledged and Agreed:

11/16/00
Date

Evelyn M. Rodriguez, M.D., M.P.H.
Division Director, DDREII
Office of Postmarketing Drug Risk Assessment
Food and Drug Administration

[FR Doc. 01–16988 Filed 7–5–01; 8:45 am]
BILLING CODE 4160–01–C