and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of request for public comments regarding an extension to an existing OMB clearance.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning Contractor Use of Interagency Motor Pool Vehicles. The clearance currently expires on April 30, 1999.

**DATES:** Comments may be submitted on or before March 1, 1999.

**ADDRESSES:** Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be submitted to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat (MVRS), 1800 F Street, NW, Room 4035, Washington, DC 20405. Please cite OMB Control No. 9000–0032, Contractor Use of Interagency Motor Pool Vehicles, in all correspondence.

**FOR FURTHER INFORMATION CONTACT:** Linda Klein, Federal Acquisition Policy Division, GSA (202) 501–3775.

**SUPPLEMENTARY INFORMATION:**

### A. Purpose

If it is in the best interest of the Government, the contracting officer may authorize cost-reimbursement contractors to obtain, for official purposes only, interagency motor pool vehicles and related services. Contractors' requests for vehicles must obtain two copies of the agency authorization, the number of vehicles and related services required and period of use, a list of employees who are authorized to request the vehicles, a listing of equipment authorized to be serviced, and billing instructions and address.

A written statement that the contractor will assume, without the right of reimbursement from the Government, the cost or expense of any use of the motor pool vehicles and services not related to the performance of the contract is necessary before the contracting officer may authorize cost-reimbursement contractors to obtain interagency motor pool vehicles and related services.

The information is used by the Government to determine that it is in the Government's best interest to authorize a cost-reimbursement contractor to obtain, for official purposes only, interageny motor pool vehicles and related services, and to provide those vehicles.

### B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average *30* minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows: Respondents, *70*; responses per respondent, *2*; total annual responses, *140*; preparation hours per response, *.5*; and total response burden hours, *70*.

*Obtaining copies of proposals:* Requester may obtain a copy of the justification from the General Services Administration, FAR Secretariat (MVRS), Room 4035, 1800 F Street, NW, Washington, DC 20405, telephone (202) 208–7312. Please cite OMB Control No. 9000–0032, Contractor Use of Interagency Motor Pool Vehicles, in all correspondence.

Dated: December 23, 1998.

**Victoria E. Moss,**

*Acting Director, Federal Acquisition Policy Division.*

[FR Doc. 98–34403 Filed 12–29–98; 8:45 am]

**BILLING CODE 6820–34–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. 98M–0136, 98M–0217, 98M–0138, 98M–0327, 98M–0328, 98M–0219, 98M–0137, 98M–0404, 98M–0200, 98M–0140, 98M–0231, 98M–0187, 98M–0139, 98M–0201, 98M–0403, 98M–0162, 97M–0084, 98M–0329, 98M–0450, 98M–0451, 98M–0251, 98M–0507, 98M–0618, 98M–0604, 98M–0619, 96M–0678, 98M–0679, 98M–0715, 98M–0711, and 98M–0725]**

### Medical Devices; List of Premarket Approval Actions

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval application (PMA) approvals. This list is intended to inform the public of the existence and the availability of summaries of safety and effectiveness of approved PMA's through the Internet and the agency's Dockets Management Branch.

**ADDRESSES:** Summaries of safety and effectiveness are available on the World Wide Web (WWW) at http://www.fda.gov/cdrh/pma page.html. Copies of summaries of safety and effectiveness are also available by submitting a written request 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 in the **SUPPLEMENTARY INFORMATION** section of this document, when submitting a written request.

**FOR FURTHER INFORMATION CONTACT:** Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

**SUPPLEMENTARY INFORMATION:** 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**. 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 on the Internet (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 the PMA approvals 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)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)), 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 all PMA applications for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure as explained previously through August 12, 1998. There were no denial actions during this period. The list is in order by PMA number and provides the manufacturer's name, the generic name or trade name, and the approval date.

TABLE 1.—LIST OF APPROVAL PMA'S FROM APRIL 24, 1997, THROUGH AUGUST 12, 1998

| PMA Number/Docket No. | Applicant | Trade Name | Approval Date |
|---|---|---|---|
| P940001/98M–0136 | Gensia, Inc. | Genesa (R) System | September 12, 1997 |
| P940015/98M–0217 | Biomatrix, Inc. | Synvisc (R) Hylan GF 20 | August 8, 1997 |
| P940016/98M–0138 | B. Braun of America, Inc. | Heparin-Induced Extracorporeal Precipitation (H.E.L.P.) System | September 19, 1997 |
| P940025/98M–0327 | Lobob Laboratories | Lobob R/RW Drop | April 30, 1998 |
| P940026/98M90328 | Lobob Laboratories | Rigid Gas Permeable Contact Lens Solution[1] and Labob C/D/S Cleaning Disinfecting Storage Solution | April 28, 1998 |
| P950031/98M–0219 | Lobob Laboratories | Lobob Cleaner | April 3, 1998 |
| P960036/98M–0137 | Mentor Corp. | Posterior Chamber Intraocular Lens | December 22, 1997 |
| P960057/98M–0404 | Gliatech, Inc. | Inhibitor, Peridural Fibrosis[1] | May 27, 1998 |
| P970002/98M–0200 | Alliance Medical Technologies, Inc. | Monostrut Cardiac Value Prosthesis[1] | September 30, 1997 |
| P970003/98M–0140 | Cyberonics, Inc. | Neurocybernetic Prothesis System NE–LYJ Stimulator, Autonomic Nerve, Implanted for Epile | July 16, 1997 |
| P970012/98M–0231 | Medtronic, Inc. | Medtronic, Kappa Pulse Generator[1] | January 30, 1998 |
| P970017/98M–0187 | Hologic, Inc. | Acoustic Bone Densitometer Sahara Clinical Bone Sonometer | March 12, 1998 |
| P970021/98M–0139 | Gynecare, Inc. | Thermal Balloon Endometrial Ablation Thermachoice Uterine Balloon Therapy (UBT) System OB–MNB–Device, Thermal Ablation, Endometrial | December 12, 1997 |
| P970038/98M–0201 | Hybritech, Inc. | Tandem Free PSA Assays[1] | March 10, 1998 |
| P970044/98M–0403 | Dornier Medical Systems, Inc. | Transurethral Microwave Thermotherapy System, Dornier Urowave Thermotherapy System, GU–MEQ–System, Hyperthermia, RF/Microwave Benign Post | May 29, 1998 |
| P970052/98M–0162 | Cardiovascular Dynamics, Inc. | Fact, Arc, Lynx, and Guardian Balloon Coronary Dilatation Catheters Percutaneous Transluminal Coronary Angioplasty (PTCA) CV–LOX–Catheters, Transluminal Coronary Angioplasty, PE | February 20, 1998 |
| P930016/S003/97M–0084 | VISX, Inc. | Excimer Laser for Ophthalmic Use | April 24, 1997 |
| P930034/S009/98M–0329 | Summit Technology, Inc. | SVS APEX Plus Excimer Laser Workstation and Emphasis Disc OP–LZS–LASER, System, Excimer | March 11, 1998 |

TABLE 1.—LIST OF APPROVAL PMA'S FROM APRIL 24, 1997, THROUGH AUGUST 12, 1998—Continued

| PMA Number/Docket No. | Applicant | Trade Name | Approval Date |
|---|---|---|---|
| P960013/98M–0450 | Pacesetter, Inc. | Tendril DX Models 1388 T/K Endocardial, Steroid Eluting Screw-In Pacing Leads and Ventritex Assure AFS Models 7010 T/K Endocardial Steroid Eluting Screw In Pacing Leads | June 20, 1997 |
| P960042/98M–0451 | Spectranetics Corp. | 12 French Laser Sheath Kit | December 9, 1997 |
| P950009/S002/98M–0251 | Neopath, Inc. | Autopap Primary Screening System | May 5, 1998 |
| P960013/98M–0450 | St. Jude Medical | Locator Steerable Stylet Model 4036 | June 15, 1998 |
| P960042/001/98M–0451 | Spectranetics Corp. | 12 French Outer Sheath | June 16, 1998 |
| P970062/98M–0507 | BMT, Inc. | Genestone 190 Lithotripter | June 24, 1998 |
| P970058/98M–0618 | R2 Technology, Inc. | M 1000 Image Checker | June 26, 1998 |
| P960011/98M–0604 | Bio-Technology General Corp. | Biolon 1% Sodium Hyaluronate Viscoelastic Surgical Aid Fluid | July 16, 1998 |
| P960018/98M–0619 | Healthcare Products Plus, Inc. | The Needlyzer The Needle Destroyer Model ND 2 | July 16, 1998 |
| P950005/98M–0678 | Cordis Webster, Inc. | Cordis Webster Diagnostic/Ablation Deflectable Tip Catheter | July 22, 1998 |
| P980015/98M–0679 | Biomedical Disposal, Inc. | Sharpx Needle Destruction Unit | August 6, 1998 |
| P970040/98M–0715 | Lunar | Achilles & Ultrasonometer | June 26, 1998 |
| P970051/98M–0711 | Cochlear Corp. | Nucleus 24 Cochlear Implant System | June 25, 1998 |
| P960034/98M–0725 | Pharmacia & UpJohn | Cleon Heparin Surface Modified (ASM) Ultraviolet light | August 12, 1998 |

[1] This means generic name.

Dated: December 15, 1998.

**D.B. Burlington,**

*Director, Center for Devices and Radiological Health.*

[FR Doc. 98–34347 Filed 12–29–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98D–1020]**

### Draft Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse To Be Used by the Consumer; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By The Consumer.'' This draft guidance addresses screening devices sold over-the-counter for testing drugs of abuse. This type of device is intended for use in the home setting as a screening test for any, or any combination, of the following five substances in urine: Amphetamine/methamphetamine, cocaine, cannabinoids, opiates, and phencyclidine.

**DATES:** Written comments concerning this draft guidance must be received by March 30, 1999.

**ADDRESSES:** Submit written requests for single copies on a 3.5'' diskette of the draft guidance entitled ''Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By The Consumer'' 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. 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Over the last several years, FDA has worked to clarify the regulation of products for use in the home setting intended to screen for drugs of abuse. On September 17, 1997, FDA released for comment a draft guidance document entitled ''Points to Consider for Approval of Home Drugs of Abuse