''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PHENERGAN (promethazine HCl) tablets, 12.5 mg and 50 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs.

Dated: June 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–11072 Filed 7–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0266]

Medical Devices; Anesthesiology Devices; Neurological Devices; Denial of Request for Change in Classification of Breathing Frequency Monitor and Electroencephalograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; denial of petition.

SUMMARY: The Food and Drug Administration (FDA) is denying the petitions submitted by IM Systems to reclassify the SleepCheck, the ActiTrac, and PAM–RL devices from class II (special controls) to class I (general controls). The agency is denying the petitions because the petitioner failed to provide sufficient new information to establish that general controls would provide reasonable assurance of the safety and effectiveness of the devices.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Classification and Reclassification of Devices Under the Medical Devices Amendments of 1976 (the 1976 Amendments)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices under the 1976 amendments are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendment devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Postamendments devices remain in class III and require premarket approval, unless: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807, subpart E of the regulations.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section of the act provides that FDA may, by rulemaking, reclassify a device based on ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc. v. FDA*, 762 F.Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.).

Regardless of whether data before the agency are past or new data, the ''new information'' upon which reclassification under section 513(e) of the act is based must consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)). In addition, § 860.123(a)(6) (21 CFR 860.123(a)(6)) provides that a reclassification petition must include a ''full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device.'' (§ 860.123(a)(6).) The ''supporting data satisfying the requirements of § 860.7'' referred to is ''valid scientific evidence.''

For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).)

II. Reclassification Under the SMDA

SMDA further amended the act to change the definition of a class II device. Under the SMDA, class II devices are those devices that cannot be classified into class I because general controls by themselves are not sufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the agency deems necessary (Section 513(a)(1)(B) of the

act). Thus, the definition of a class II device was changed from ''performance standards'' to ''special controls.'' In order for a device to be reclassified from class II to class I, the agency must determine that special controls are not necessary to provide reasonable assurance of its safety and effectiveness.

III. Background

In the **Federal Register** of July 16, 1982 (47 FR 31130), FDA issued a final rule classifying the breathing frequency monitor into class II (§ 868.2375). The preamble to the proposal to classify the device included the recommendation of the Anesthesiology Device Panel. The Panel identified the following risks to health associated with the use of the devices: (1) Failure of the device or alarm may cause abnormal conditions to go undiscovered and result in serious patient injury or death and (2) if the device does not monitor the patient's breathing frequency accurately he/she may receive incorrect therapy.

In the **Federal Register** of September 4, 1979 (44 FR 51726), FDA issued a final rule classifying the electroencephalograph into class II (§ 882.1400 (21 CFR 882.1400)). The preamble to the proposal to classify the device included the recommendation of the Neurological Device Panel. The Panel's recommendation identified the following risks to health associated with use of the device: (1) Misuse of the device as a result of using untrained persons may result in improper diagnosis and treatment; (2) misdiagnosis of the physiological symptoms could cause a misdiagnosis and lead to improper treatment of the patient's neurological condition; and (3) electrical shock could be associated with current leakage of the device, making it hazardous because the device makes a low resistance contact with the patient.

On August 18, 2004, IM Systems submitted three petitions requesting FDA to reclassify the SleepCheck device, the ActiTrac, and PAM–RL devices from class II to class I (Ref. 1). Under 21 CFR 860.120(b) the reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within that generic type of device.

IV. Device Description

The SleepCheck device is classified within the generic type of device called the breathing frequency monitor (§ 868.2375). FDA identifies the breathing frequency monitor as a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate, averaged over time, is outside operator settable alarm limits.

The ActiTrac and PAM–RL devices are classified within the generic type of device called the electroencephalograph (§ 882.1400). FDA identifies the electroencephalograph as a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

V. FDA's Decision

After reviewing both the reclassification petitions and the petitioner's responses to our subsequent requests for information, FDA has found that the petitions do not contain any valid scientific evidence to support a conclusion that general controls would provide reasonable assurance of the devices' safety and effectiveness for their intended uses or that special controls are not necessary to provide reasonable assurance of the safety and effectiveness of the devices. Therefore, FDA is denying the petitions for reclassification of these device types.

VI. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These references may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petitions from IM Systems for the reclassification of the SleepCheck device, PAM–RL device, and the ActiTrac device, dated August 18, 2004.

Dated: July 5, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–11115 Filed 7–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Method for Expanding Allodepleted Antigen Specific T Cells

Description of Technology: Available for licensing and commercial development are methods of producing a population of purified non-alloreactive antigen-specific T cells that recognize an antigen of interest. Thus, the population of donor T cells can be used to produce immune response against the antigen of interest (e.g., cytomegalovirus) in a recipient without producing an immune response to the recipient. Currently available methods for isolating and expanding antigen-specific T cells can be inefficient and produce populations of cells that include donor-reactive T cells. The present method enables rapid production of populations of T cells that recognize an antigen of interest but are depleted for alloreactive T cells: A population of donor T cells is contacted with a population of irradiated recipient antigen presenting cells (T–APCs) to produce a population of alloreactive T cells. The alleractive T cells are removed by purification with an antibody that specifically binds a cell surface marker (e.g., CD25, CD69, CD38 or CD71). The population of allo-depleted donor cells is then contacted with donor T antigen presenting cells (T–APCs) expressing an antigen of interest and produces a population of donor allo-depleted activated CD4 and CD8 T cells.

Applications: Immune response to opportunistic infectious in immuno-compromised transplant or graft recipients.

Market: (1) Cytomegalovirus; (2) General post-transplant opportunistic infections.

Inventors: J. Joseph Melenhorst and A. John Barrett (NHLBI).

Publications:

1. JJ Melenhorst, TH Brummendorf, M Kirby, PM Lansdorp, AJ Barrett. ''CD8+T cells in large granular lymphocyte