receiving payments pursuant to HHS and Department of Agriculture benefit programs, and to verify their continued eligibility for such benefits. SPAAs will contact affected individuals and seek to verify the information resulting from the match before initiating any adverse actions based on the match results.

C. Authority for Conducting the Match

The authority for conducting the matching program is contained in section 402(a)(6) of the Social Security Act [42 U.S.C. 602(a)(6)].

D. Records To Be Matched

VA will disclose records from its Privacy Act system of records entitled ''Compensation, Pension, Education and Rehabilitation Records.'' (58 VA 21/22 first published at 41 FR 9294 (March 3, 1976), and last amended at 70 FR 34186 (June 13, 2005)). VA's disclosure of information for use in this computer match is listed as a routine use in this system of records.

VA, as the source agency, will prepare electronic files containing the names and other personal identifying data of eligible veterans receiving benefits. These records are matched electronically against SPAA files consisting of data regarding monthly Medicaid, Temporary Assistance to Needy Families (TANF), general assistance, and Food Stamp beneficiaries.

1. The electronic files provided by the SPAAs will contain client names and Social Security numbers (SSNs.)

2. The resulting output returned to the SPAAs will contain personal identifiers, including names, SSNs, employers, current work or home addresses, etc.

E. Inclusive Dates of the Matching Program

The effective date of the matching agreement and date when matching may actually begin shall be at the expiration of the 40-day review period for OMB and Congress, or 30 days after publication of the matching notice in the **Federal Register**, whichever date is later. The matching program will be in effect for 18 months from the effective date, with an option to renew for 12 additional months, unless one of the parties to the agreement advises the others by written request to terminate or modify the agreement.

[FR Doc. 06–6226 Filed 7–13–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2005P–0300 and 2005P–0319]

Determination That PHENERGAN (Promethazine Hydrochloride) Tablets, 12.5 Milligrams and 50 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that PHENERGAN (promethazine hydrochloride (HCl)) tablets, 12.5 milligrams (mg) and 50 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for promethazine HCl tablets, 12.5 mg and 50 mg.

FOR FURTHER INFORMATION CONTACT: Quynh Nguyen, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

PHENERGAN (promethazine HCl) tablets, 12.5 mg and 50 mg, are the subject of approved NDA 7–935 held by Wyeth Pharmaceuticals, Inc. (Wyeth). PHENERGAN (promethazine HCl) tablets are indicated for, among other things, certain types of allergic reactions and sedation. Wyeth's NDA 7–935 was originally approved in 1951. In 1971, under the Drug Efficacy Study Implementation (DESI), FDA concluded that promethazine HCl tablets were effective or probably effective for the indications described in the **Federal Register** notice published on June 18, 1971 (DESI 6290, 36 FR 11758). Wyeth discontinued sale of the 12.5 mg and 50 mg tablets in 2004. Amide Pharmaceutical, Inc., and Peter S. Reichertz submitted citizen petitions dated July 28, 2005 (Docket No. 2005P–0300/CP1), and August 10, 2005 (Docket No. 2005P–0319/CP1), respectively, under 21 CFR 10.30, requesting that the agency determine, as described in § 314.161, whether PHENERGAN (promethazine HCl) tablets, 12.5 mg and 50 mg, were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Wyeth's PHENERGAN (promethazine HCl) tablets, 12.5 mg and 50 mg, were not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, we note that promethazine HCl is a widely used product that has been marketed for many decades in many dosage forms. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate that PHENERGAN tablets, 12.5 mg and 50 mg, were withdrawn for reasons of safety or effectiveness.

After considering the citizen petitions (including comments submitted) and reviewing agency records, FDA determines that for the reasons outlined previously, Wyeth's PHENERGAN (promethazine HCl) tablets, 12.5 mg and 50 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list PHENERGAN (promethazine HCl) tablets, 12.5 mg and 50 mg, in the

''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