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 SPAAs 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 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]
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 preamendments 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 declaring the device to be substantially equivalent, under section 513(j) 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 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 Bontos 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, 767 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1067 (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. 360(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/or appropriate actions the agency deems necessary (Section 513(a)(1)(B) of the