ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Mother-Child Interaction	1,900	1	0.25	475
Teacher Questionnaire	950	1	0.50	475
Year 2 Total	5,700			3,240
Year 3 (2009):				
Parent Interview	380	1	1.00	380
Child Assessment	380	1	1.16	441
Child Interview	380	1	0.25	95
Mother-Child Interaction	760	1	0.25	190
Teacher Questionnaire	380	1	0.50	190
Year 3 Total	2,280			1,296

Estimated Total Burden Hours: 6,480.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: July 10, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–6227 Filed 7–13–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974, as Amended; Computer Matching Program

AGENCY: ACF, HHS.

ACTION: Notice of a computer matching program.

SUMMARY: In compliance with the Privacy Act of 1974, as amended by Pub. L. 100–503, the Computer Matching and Privacy Protection Act of 1988, we are publishing a notice of a computer matching program. The purpose of this computer match is to identify specific individuals who are receiving benefits from the VA and also receiving payments pursuant to various benefit programs administered by both HHS and Department of Agriculture. ACF will facilitate this program on behalf of the State Public Assistance Agencies (SPAAs) that participate in the Public Assistance Reporting Information System (PARIS) for verification of continued eligibility for public assistance. The match will utilize Department of Veterans Affairs (VA) records and SPAA records.

DATES: ACF will file a report of the subject matching program with the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Government Reform of the House of Representatives, and the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB). The dates for the matching program will be effective as indicated below.

ADDRESSES: Interested parties may comment on this notice by writing to the Director, Office of Financial Services, Office of Administration, 370 L'Enfant Promenade, SW., Washington, DC 20047. All comments received will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: Director, Office of Financial Services, Office of Administration, 370 L'Enfant Promenade, SW., Washington, DC 20047. Telephone Number (202) 401–7237.

SUPPLEMENTARY INFORMATION: Pub. L. 100–503, the Computer Matching and Privacy Protection Act of 1988, amended the Privacy Act (5 U.S.C. 552a) by adding certain protections for individuals applying for and receiving federal benefits. The law regulates the use of computer matching by federal agencies when records in a system of records are matched with other federal, state and local government records.

Federal agencies which provide or receive records in computer matching programs must:

1. Negotiate written agreements with source agencies;
2. Provide notification to applicants and beneficiaries that their records are subject to matching;
3. Verify match findings before reducing, suspending, or terminating an individual's benefits or payments;
4. Furnish detailed reports to Congress and OMB; and,
5. Establish a Data Integrity Board that must approve matching agreements.

This computer matching program meets the requirements of Pub. L. 100–503.

Dated: June 21, 2006.

Curtis L. Coy,

Deputy Assistant Secretary for Administration, ACF.

Notice of Computer Matching Program

A. Participating Agencies

VA and the SPAAs.

B. Purpose of the Match

To identify specific individuals who are receiving benefits from VA and also

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]

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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