

(DPCDD), Enterprise Databases Group, Office of Information Services, CMS, Mail stop N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.-3 p.m., eastern daylight time.

**FOR FURTHER INFORMATION CONTACT:**

Walter Stone, Senior Paralegal Specialist, Division of Data Liaison and Distribution, Enterprise Databases Group, Office of Information Services, CMS, Mail stop N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. The telephone number is (410) 786-5357, or facsimile (410) 786-5636.

**SUPPLEMENTARY INFORMATION:**

**I. Description of the Matching Program**

*A. General*

The Computer Matching and Privacy Protection Act of 1988 (Public Law (Pub. L.) 100-503), amended the Privacy Act (5 U.S.C. 552a) by describing the manner in which computer matching involving Federal agencies could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 100-508) further amended the Privacy Act regarding protections for such individuals. The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records (SOR) are matched with other Federal, state, or local government records. It requires Federal agencies involved in computer matching programs to:

1. Negotiate written agreements with the other agencies participating in the matching programs;
2. Obtain the Data Integrity Board approval of the match agreements;
3. Furnish detailed reports about matching programs to Congress and OMB;
4. Notify applicants and beneficiaries that the records are subject to matching; and,
5. Verify match findings before reducing, suspending, terminating, or denying an individual's benefits or payments.

*B. CMS Computer Matches Subject to the Privacy Act and/or Privacy Rule*

CMS has taken action to ensure that all CMPs that this Agency participates in comply with the requirements of the Privacy Act of 1974, as amended, and the Health Insurance Portability and Accountability Act (45 CFR parts 160

and 164, 65 FR 82462 (12-28-00), subparts A and E.

Dated: August 1, 2003.

**Thomas A. Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

**Computer Match No. 2002-02**

*Name:*

"Verification of CHAMPUS/TRICARE Eligibility for Military Health System Beneficiaries Who are Medicare Eligible and Under the Age of 65."

*Security Classification:*

Level Three Privacy Act Sensitive

*Participating Agencies:*

The Centers for Medicare & Medicaid Services (CMS); and Department of Defense (DoD), Manpower Data Center (DMDC), Defense Enrollment and Eligibility Reporting System Office (DEERS), and the Office of the Assistant Secretary of Defense (Health Affairs)/TRICARE Management Activity (TMA).

*Authority for Conducting Matching Program:*

This agreement implements the information matching provisions of the National Defense Authorization Acts (NDAA) for Fiscal Years (FY) 1992 and 1993 (PL 102-190) § 704, which provide for reinstatement of CHAMPUS as second payer for beneficiaries entitled to Medicare on the basis of disability/ESRD *only if they also enroll in Part B*, and the 1996 NDAA (Public Law 104-106) § 732, which amended § 1086(d) of title 10, U.S.C., and directed the administering Secretaries to develop a mechanism for notifying beneficiaries of their ineligibility for CHAMPUS when loss of eligibility is due to disability status.

*Purpose(s) of the Matching Program:*

The purpose of this agreement is to establish the conditions, safeguards and procedures under which CMS will disclose Medicare enrollment information to the DoD. This disclosure will provide TMA with the information necessary to determine if an individual is eligible to receive extended TRICARE coverage.

Current law requires TMA to discontinue military health care benefits to disabled individuals when they become eligible for Medicare Part A because of disability or End Stage Renal Disease (ESRD), unless they are enrolled in Medicare Part B. In order for TMA to meet these requirements, CMS agrees to disclose Part A and Part B enrollment data on this dual eligible population, which will be used to determine a

beneficiary's eligibility for continued care under TRICARE. DMDC/DEERS will receive the results of the computer match and provide the information to TMA for use in its program.

*Categories of Records and Individuals Covered by the Match:*

DEERS will furnish CMS with an electronic file on a monthly basis extracted from DEERS' system of records identified as S322.50, entitled "Defense Eligibility Records (DER)," containing social security numbers (SSN) for all DoD eligible beneficiaries under the age of 65 who may also be eligible for Medicare benefits. CMS will match the DEERS file against its "Enrollment Database" system of records (formerly known as the Health Insurance Master Record), System No. 09-70-0502, and will validate the identification of the beneficiary and provide the Health Insurance Claims Number (HICN) that matches against the SSN and date of birth provided by DEERS, and also provide the Medicare Part A entitlement status and Part B enrollment status of the beneficiary. CMS's data will help TMA to determine a beneficiary's eligibility for continued care under TRICARE. DEERS will receive the results of the computer match and provide the information provided to TMA for use in its program.

*Inclusive Dates of the Match:*

The Matching Program shall become effective no sooner than 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, whichever is later. The matching program will continue for 18 months from the effective date and may be renewed every 12 months thereafter, as long as the statutory language for the match exists and other conditions are met.

[FR Doc. 03-20777 Filed 8-15-03; 8:45 am]

BILLING CODE 4120-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003N-0335]

**Eli Lilly and Co. et al.; Withdrawal of Approval of 80 New Drug Applications and 75 Abbreviated New Drug Applications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 80 new drug applications (NDAs) and 75 abbreviated new drug applications (ANDAs). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the

approval of the applications be withdrawn.

**EFFECTIVE DATE:** September 17, 2003

**FOR FURTHER INFORMATION CONTACT:** Florine P. Purdie, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their requests, waived their opportunity for a hearing.

Application No.	Drug	Applicant
NDA 0-159	Sulfapyridine Tablets.	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
NDA 0-734	Histamine Phosphate Injection.	Do.
NDA 5-970	Sotradecol (sodium tetradecyl sulfate) Injection.	Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 7-898	Benemid (probenecid) Tablets.	Merck & Co., Inc., Sunneytown Pike, P.O. Box 4, BLA-20, West Point, PA 19486.
NDA 8-048	Xylocaine (lidocaine) Ointment.	AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803-8355.
NDA 8-228	Hydrocortone (hydrocortisone acetate) Acetate Injectable Suspension.	Merck & Co., Inc.
NDA 8-565	Thiosulfil (sulfamethizole) Tablets and Suspension.	Wyeth Pharmaceuticals.
NDA 9-489	Pathilon (tridehixethyl) Tablets.	Lederle Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 10-210	Metymid Ophthalmic (prednisolone acetate and sulfacetamide sodium).	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 10-220	Hypaque-M 75% and 90% Hypaque Compound (diatrizoate meglumine and diatrizoate sodium) Injection.	Amersham Health, 101 Carnegie Center, Princeton, NJ 08540-6231.
NDA 10-348	Sparine (promazine hydrochloride (HCl)) Tablets.	Wyeth Pharmaceuticals.
NDA 10-496	Xylocaine-MPF 5% Solution With Glucose 7.5% (lidocaine HCl and dextrose).	AstraZeneca Pharmaceuticals LP.
NDA 10-562	Hydeltra-T.B.A. (prednisolone tebutate).	Merck & Co., Inc.
NDA 10-753	Estradurin (polyestradiol phosphate) Injection.	Wyeth Pharmaceuticals.
NDA 10-942	Sparine (promazine HCl) Syrup and Concentrate.	Do.
NDA 11-338	Fluothane Inhalation (halothane USP).	Do.
NDA 11-418	Dimetane Ten Injectable (brompheniramine maleate).	Do.
NDA 11-673	Tepanil (diethylpropion HCl) Tablets.	3M Pharmaceuticals, 3M Center, Bldg. 270-3A-01, St. Paul, MN 55144-1000.
NDA 11-958	Hydropres (reserpine and hydrochlorothiazide).	Merck & Co., Inc.
NDA 12-383	ColBenemid (probenecid and colchicine) Tablets.	Do.
NDA 12-418	Akineton (biperiden lactate) Injection.	Abbott Laboratories, 200 Abbott Park Rd., Abbott Park, IL 60064-6157.
NDA 12-489	Exna (benzthiazide) Tablets.	Wyeth Pharmaceuticals.

Application No.	Drug	Applicant
NDA 12-731	Decaspray (dexamethasone) Topical Aerosol.	Merck & Co., Inc.
NDA 12-882	Isordil Tembids (isosorbide dinitrate) Controlled-Release Tablets and Capsules.	Wyeth Pharmaceuticals.
NDA 12-947	Artane (trihexyphenidyl HCl) Sustained-Release Capsules.	Lederle Laboratories.
NDA 13-264	Hydromox (quinethazone) Tablets.	Wyeth Pharmaceuticals.
NDA 13-334	Decadron With Xylocaine Injection (dexamethasone sodium phosphate and lidocaine HCl).	Merck & Co., Inc.
NDA 13-378	Dymelor (acetohexamide) Tablets.	Eli Lilly and Co.
NDA 13-731	Bilopaque (tyropanoate sodium) Capsules.	Amersham Health.
NDA 14-763	Citanest Plain (prilocaine HCl) and Citanest Forte (prilocaine HCl and epinephrine) Injection.	AstraZeneca Pharmaceuticals LP.
NDA 15-052	Atabrine (quinacrine HCl) Injection.	Abbott Laboratories.
NDA 15-921	Haldol (haloperidol) Tablets.	Ortho-McNeil Pharmaceutical, Inc., c/o Johnson & Johnson Pharmaceutical Research & Development, L.L.C., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560-0200.
NDA 15-922	Haldol (haloperidol lactate) Oral Concentrate.	Do.
NDA 16-192	Sorbitrate (isosorbide dinitrate) Oral 5 milligram (mg) and 10 mg Tablets.	AstraZeneca Pharmaceuticals LP.
NDA 16-675	Decadron LA (dexamethasone acetate) Sterile Suspension.	Merck & Co., Inc.
NDA 16-776	Sorbitrate (isosorbide dinitrate) Chewable Tablets.	AstraZeneca Pharmaceuticals LP.
NDA 17-048	Peptavlon (pentagastrin) for Subcutaneous Injection.	Wyeth Pharmaceuticals.
NDA 17-406	Dicopac Kit.	Amersham Health.
NDA 17-503	Combipres (clonidine HCl and chlorthalidone) Tablets.	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877-0368.
NDA 17-638	Thypinone (protirelin) Injection.	Abbott Laboratories.
NDA 17-653	Technetium Tc-99m HEDSPA Multidose Kit.	Amersham Health.
NDA 17-691	Diprosone (betamethasone dipropionate) Ointment, 0.05%.	Schering Corp.
NDA 17-751	Duranest (etidocaine HCl) Injection.	AstraZeneca Pharmaceuticals LP.
NDA 17-775	Technetium Tc-99m HSA Kit.	Medi-Physics, Inc., d.b.a., Nycomed Amersham Imaging, 101 Carnegie Center, Princeton, NJ 08540-6231.
NDA 17-784	Technetium Tc-99m TSC Kit.	Amersham Health.
NDA 17-980	Mazanor (mazindol) Tablets.	Wyeth Pharmaceuticals.
NDA 17-982	Amipaque (metrizamide) Injection.	Amersham Health.
NDA 17-992	Crescormon (somatropin, pituitary).	Genentech, Inc., 1 DNA Way, MS#48, South San Francisco, CA 94080-4990.
NDA 18-021	Asendin (amoxapine) 25 mg, 50 mg, 100 mg, and 150 mg Tablets.	Wyeth Pharmaceuticals.

Application No.	Drug	Applicant
NDA 18-153	Beclovent (beclomethasone dipropionate) Inhalation Aerosol.	GlaxoSmithKline, Five Moore Dr., Research Triangle Park, NC 27709.
NDA 18-280	Yutopar (ritodrine HCl) Tablets and Injection.	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
NDA 18-290	Secretin-Ferring Powder for Injection.	Ferring Pharmaceuticals, Inc., 120 White Plains Rd., Suite 400, Tarrytown, NY 10591.
NDA 18-381	Regular Purified Pork Insulin.	Novo Nordisk Pharmaceuticals, Inc., 100 College Rd. West, Princeton, NJ 08540.
NDA 18-383	Lente Purified Pork Insulin Zinc Suspension.	Do.
NDA 18-450	Nitropress (sodium nitroprusside) Injection.	Abbott Laboratories.
NDA 18-623	NPH Purified Pork Isophane Insulin Suspension.	Novo Nordisk Pharmaceuticals, Inc.
NDA 19-112	Ventolin (albuterol sulfate) Tablets.	GlaxoSmithKline.
NDA 19-269	Ventolin (albuterol sulfate) Inhalation Solution, 0.5%.	Do.
NDA 19-280	Cyklokapron (tranexamic acid) Tablets.	Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199.
NDA 19-489	Ventolin (albuterol sulfate) Rotacaps Inhalation Powder.	GlaxoSmithKline.
NDA 19-536	Inderal (propranolol HCl) Oral Suspension.	Wyeth Pharmaceuticals.
NDA 19-773	Ventolin (albuterol sulfate) Nebules Inhalation Solution, 0.083%.	GlaxoSmithKline.
NDA 19-836	Supprelin (histrelin acetate) Injection.	Shire Pharmaceutical Development, Inc., 1801 Research Blvd., Suite 600, Rockville, MD 20850.
NDA 20-063	Technetium Tc-99m Red Blood Cell Kit.	Cadema Corp., c/o Number One Corporation, 50 Washington St., Norwalk, CT 06854.
NDA 20-924	Cernevit-12 Multivitamins.	Baxter Healthcare Corp., Route 120 and Wilson Rd., RLT-10, Round Lake, IL 60073-0490.
NDA 21-384	Duranest (etidocaine HCl and epinephrine bitartrate) Injection.	Dentsply Pharmaceutical, 3427 Concord Rd., York, PA 17402.
NDA 50-202	Chloromycetin Hydrocortisone Ophthalmic (chloramphenicol and hydrocortisone acetate for ophthalmic suspension USP).	Parkdale Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
NDA 50-251	Aureomycin (chlortetracycline HCl) Capsules.	Wyeth Pharmaceuticals.
NDA 50-257	Declomycin (demeclocycline HCl) Syrup Drops.	Do.
NDA 50-263	Achromycin V (tetracycline HCl) Suspension and Drops.	Do.
NDA 50-264	Achromycin (tetracycline HCl).	Do.
NDA 50-315	Minocin (minocycline HCl) Capsules.	Do.
NDA 50-451	Minocin (minocycline HCl) Tablets.	Do.
NDA 50-483	Nebcin (tobramycin sulfate) Sensitivity Disk.	Eli Lilly and Co.
NDA 50-484	Cerubidine (daunorubicin HCl) Injection.	Wyeth Pharmaceuticals.
NDA 50-493	Topicycline (tetracycline HCl) Solution.	Shire Pharmaceutical Development, Inc.

Application No.	Drug	Applicant
NDA 50-508	Cyclapen-W (cyclacillin) Oral Suspension.	Wyeth Pharmaceuticals.
NDA 50-509	Cyclapen-W (cyclacillin) Tablets.	Do.
NDA 50-544	Netromycin (netilmicin sulfate) Injection.	Schering Corp.
NDA 50-633	Cefpiramide Sodium Injection.	Wyeth Pharmaceuticals.
ANDA 60-007	Pen-Vee K for Oral Solution (penicillin V potassium for oral solution), 125 mg (base)/5 milliliters (mL) and 250 mg (base)/5 mL.	Do.
ANDA 60-462	Garamycin (gentamicin sulfate) Cream, 0.1%.	Schering Corp.
ANDA 61-151	Nilstat (nystatin) tablets USP) Oral Tablets, 500,000 units.	Lederle Laboratories.
ANDA 61-325	Nilstat (nystatin) Vaginal Tablets, 100,000 units.	Do.
ANDA 61-444	Nilstat (nystatin) Ointment, 100,000 units/gram (g).	Do.
ANDA 61-445	Nilstat (nystatin) Cream, 100,000/g.	Do.
ANDA 61-633	Robimycin (erythromycin) Robitabs, 250 mg.	A.H. Robins Co., P.O. Box 8299, Philadelphia, PA 19101-8299.
ANDA 61-734	Robitet (tetracycline HCl capsules USP) Robicaps, 250 mg and 500 mg.	Wyeth Pharmaceuticals.
ANDA 62-120	Wymox (amoxicillin) Capsules, 250 mg and 500 mg.	Do.
ANDA 62-302	Otobiotic (polymyxin B sulfate and hydrocortisone otic solution USP) Sterile Otic Solution.	Schering Corp.
ANDA 62-579	Precef (ceforanide) for Injection.	Apothecon, c/o Bristol-Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543-4500.
ANDA 62-821	Cephalexin Capsules USP, 250 mg.	TEVA Pharmaceutical USA, 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454.
ANDA 62-823	Cephalexin Capsules USP, 500 mg.	TEVA Pharmaceutical USA.
ANDA 62-860	Ampicillin for Injection.	Apothecon.
ANDA 62-867	Cephalexin for Oral Suspension USP, 250 mg/5mL.	TEVA Pharmaceutical USA.
ANDA 62-873	Cephalexin for Oral Suspension USP, 125 mg/5mL.	Do.
ANDA 62-961	Cefadyl (cephapirin) for Injection.	Apothecon.
ANDA 63-120	Tobramycin Sulfate Injection USP, 2 mL vial, 40 mg/mL.	AstraZeneca LP.
ANDA 63-122	Tobramycin Sulfate Injection USP, 40 mg/mL.	Do.
ANDA 64-131	Trimox (amoxicillin tablets USP), Tablets, 125 mg and 250 mg.	Apothecon.
ANDA 70-128	Propranolol HCl Tablets USP, 80 mg.	ESI Lederle, c/o Lederle Laboratories, 401 North Middletown Rd., Pearl River, NY 10965-1299.
ANDA 70-318	Haloperidol Oral Solution USP (Concentrate), 2 mg/mL.	Alpharma, U.S. Pharmaceuticals Division, 200 Elmora Ave., Elizabeth, NJ 07207.
ANDA 70-757	Propranolol HCl Tablets USP, 80 mg.	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.

Application No.	Drug	Applicant
ANDA 70-814	Propranolol HCl Tablets USP, 10 mg.	Do.
ANDA 70-815	Propranolol HCl Tablets USP, 20 mg.	Do.
ANDA 70-816	Propranolol HCl Tablets USP, 40 mg.	Do.
ANDA 70-817	Propranolol HCl Tablets USP, 60 mg.	Do.
ANDA 71-495	Propranolol HCl Tablets USP, 60 mg.	ESI Lederle.
ANDA 71-496	Propranolol HCl Tablets USP, 90 mg.	Do.
ANDA 71-673	Doxepin HCl Capsules USP, 50 mg.	Do.
ANDA 71-674	Doxepin HCl Capsules USP, 75 mg.	Do.
ANDA 71-675	Doxepin HCl Capsules USP, 100 mg.	Do.
ANDA 71-676	Doxepin HCl Capsules USP, 150 mg.	Do.
ANDA 71-685	Doxepin HCl Capsules USP, 10 mg.	Do.
ANDA 71-686	Doxepin HCl Capsules USP, 25 mg.	Do.
ANDA 72-026	Fentanyl Citrate and Droperidol Injection.	AstraZeneca LP.
ANDA 72-687	Foamicon (alumina and magnesium trisilicate tablets USP), 80 mg and 20 mg.	Novartis Consumer Health, Inc., 200 Kimball Dr., Parsippany, NJ 07054-0622.
ANDA 73-080	Loperamide HCl Capsules USP, 2mg.	Roxane Laboratoires, Inc., P.O. Box 16532, Columbus, OH 43216.
ANDA 73-403	Questran (cholestyramine) Tablets, 800 mg and 1,000 mg.	Bristol-Myers Squibb Co.
ANDA 73-440	Desoximetasone Ointment USP, 0.25%.	Altana, Inc., 60 Baylis Rd., Melville, NY 11747.
ANDA 73-494	Thiothixene HCl Intensol Oral Solution (Concentrate), 5 mg/mL.	Roxane Laboratories, Inc.
ANDA 74-036	Piroxicam Capsules USP, 10 mg and 20 mg.	SCS Pharmaceuticals, Box 5110, Chicago, IL 60680-9889.
ANDA 74-734	Iopamidol Injection USP, 61% and 76%.	Faulding Pharmaceuticals, Mack-Cali Centre 11, 650 From Rd., Paramus, NJ 07652.
ANDA 75-100	Bromocriptine Mesylate Capsules USP, 5 mg.	Lek, Pharmaceutical and Chemical Co. d.d., c/o Lek Services, Inc., 115 North Third St., Suite 301, Wilmington, NC 28401.
ANDA 75-223	Labetalol HCl Tablets USP, 100 mg, 200 mg, and 300 mg.	Apothecon.
ANDA 80-081	Sulfadiazine Tablets USP, 500 mg.	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 80-254	Testosterone Propionate Injection USP, 50 mg/mL.	Eli Lilly and Co.
ANDA 80-686	Folic Acid Tablets USP, 1 mg.	Impax Laboratories, Inc.
ANDA 80-781	Hydrocortisone Tablets USP, 20 mg.	Do.
ANDA 80-785	Tripelennamine HCl Tablets USP, 50 mg.	Do.
ANDA 80-853	Betalin-S (thiamine HCl injection USP), 100 mg/mL.	Eli Lilly and Co.
ANDA 83-209	Estratab Tablets (esterified estrogens tablets USP) 0.625 mg.	Solvay Pharmaceuticals, Inc.
ANDA 83-488	Estrogenic Substance (sterile estrone suspension USP) for Injection.	Wyeth Pharmaceuticals.

Application No.	Drug	Applicant
ANDA 83-607	Hydrochlorothiazide Tablets USP.	Impax Laboratories, Inc.
ANDA 83-720	Probenecid and Colchicine Tablets USP, 500 mg/0.5 mg.	Do.
ANDA 83-789	Furacin (nitrofurazone) Topical Cream.	Shire Pharmaceutical Development, Inc.
ANDA 83-967	Trichlormethiazide Tablets USP, 4 mg.	Impax Laboratories, Inc.
ANDA 84-029	Hydrochlorothiazide Tablets USP, 25 mg.	Do.
ANDA 84-444	Phenaphen with Codeine (acetaminophen and codeine phosphate capsules USP), No. 2 Capsules, 325 mg/15 mg.	A.H. Robins Co.
ANDA 84-541	Propantheline Bromide Tablets USP, 15 mg.	Impax Laboratories, Inc.
ANDA 85-057	Tylenol With Codeine (acetaminophen and codeine phosphate oral solution USP) Elixir, 120 mg/12 mg.	Ortho-McNeil Pharmaceuticals, Inc., c/o Johnson & Johnson Pharmaceutical Research and Development, L.L.C., 920 Route 202 South, P.O. Box 300, Raritan, NJ 08869-0602.
ANDA 85-856	Phenaphen-650 With Codeine (acetaminophen and codeine phosphate tablets USP) Tablets, 650 mg/30 mg.	A.H. Robbins Co.
ANDA 86-405	Sorbitrate (isosorbide dinitrate tablets USP), 20 mg.	AstraZeneca Pharmaceuticals LP.
ANDA 86-530	Seconal (secobarbital sodium) Suppositories.	Eli Lilly and Co.
ANDA 86-683	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Purpac Pharmaceutical Co.
ANDA 86-715	Estratab Tablets (esterified estrogens tablets USP), 0.3 mg.	Solvay Pharmaceuticals.
ANDA 87-158	Fluonid (fluocinolone acetonide) Solution, 0.01%.	Allergan, 2525 Dupont Dr., P.O. Box 19534, Irvine, GA 92623-9534.
ANDA 87-847	Atropine and Demerol (atropine sulfate and meperidine HCl) Injection, 0.4 mg/75 mg/mL.	Abbott Laboratories.
ANDA 87-848	Atropine and Demerol (atropine sulfate and meperidine HCl) Injection, 0.4 mg/100 mg/mL.	Do.
ANDA 87-853	Atropine and Demerol (atropine sulfate and meperidine HCl) Injection, 0.4 mg/50 mg/mL.	Do.
ANDA 87-864	Triple Sulfa Vaginal Cream (sulfathiazole, sulfacetamide, and sulfabenzamide).	Alpharma.
ANDA 88-125	Sorbitrate (isosorbide dinitrate tablets USP), 40 mg.	AstraZeneca Pharmaceuticals, LP.
ANDA 88-343	Bromanyl (bromodiphenhydramine HCl and codeine phosphate) Cough Syrup, 12.5 mg/5 mL and 10 mg/5 mL).	Alpharma.
ANDA 89-561	Chlorpropamide Tablets USP, 100 mg.	Lederle Laboratories.
ANDA 89-562	Chlorpropamide Tablets USP, 250 mg.	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 17, 2003

Dated: July 18, 2003.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 03-20949 Filed 8-15-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0294]

#### Anesthetic and Life Support Drugs Advisory Committee; Amendment of Notice

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

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Anesthetic and Life Support Drugs Advisory Committee. This meeting was announced in the **Federal Register** of July 31, 2003 (68 FR 44955). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** Johanna M. Clifford, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12529. Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 31, 2003, FDA announced that a meeting of the Anesthetic and Life Support Drugs Advisory Committee would be held on September 9 and 10, 2003. On page 44956, in the first column, the *Agenda* portion of the meeting is amended to read as follows:

*Agenda:* On September 10, 2003, the committee will discuss the abuse liability of and Risk Management Plans for Palladone (Hydromorphone Hydrochloride) Purdue Pharma, LP, a

modified-release hydromorphone drug product indicated for the treatment of moderate to severe pain in opioid tolerant patients.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 12, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 03-20951 Filed 8-15-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Dermatologic and Ophthalmic Drugs Advisory Committee.

*General Function of the Committee:*

To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on September 9 and 10, 2003, from 8 a.m. to 5:30 p.m.

*Location:* Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* Kimberly Littleton Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On September 9, 2003, the committee will discuss the efficacy and safety of submission tracking number biologics licensing application 125075/0, Efalizumab (Raptiva) by Genentech, Inc., to be used in the treatment of adult patients with moderate to severe plaque psoriasis. On September 10, 2003, the committee will discuss new drug application (NDA) 21-576, Methyl Aminolevulinate Hydrochloride (methyl

aminolevulinate cream, 168 milligram/gram) by PhotoCure ASA, for treatment of basal cell carcinoma.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 1, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 3, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kimberly Littleton Topper at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 12, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 03-20952 Filed 8-15-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D-0349]

#### Draft Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Control Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Reviewers: Instructions and Template for Chemistry,