Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–1 Human Subjects Requirement
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000
AR–12 Lobbying Restrictions
AR–15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic

Assistance Number

This program is authorized under sections 301(a) and 317(k)(1)of the Public Health Service Act, (42 U.S.C. sections 247b(k)(1) and 247b(k)(2)), as amended. The Catalog of Federal Domestic Assistance (CFDA) number is 93.283.

J. Where To Obtain Additional Information

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave you name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Locke Thompson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: (404) 842–2749, Email address: lxt1@cdc.gov.

See also the CDC homepage on the Internet to obtain a copy of this announcement: http://www.cdc.gov

For program technical assistance, contact: Linda Moyer, Centers for Disease Control and Prevention, National Center for Infectious Diseases, Division of Rickettsial Diseases, Hepatitis Branch, 1600 Clifton Rd, NE., Atlanta, GA 30333, Telephone: (404) 639–2709, E-mail address: lam1@cdc.gov.

Dated: June 4, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–14700 Filed 6–9–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1590]

Merck & Co., Inc., et al.; Withdrawal of Approval of 32 New Drug Applications and 48 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 32 new drug applications (NDA's) and 48 abbreviated new drug applications (ANDA's). 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: JULY 12, 1999.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, 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 request, waived their opportunity for a hearing.

Application No.	Drug	Applicant
NDA 5–620	Mannitol Injection	Merck & Co., Inc., P.O. Box 4, BLA–20, West Point, PA 19486.
NDA 6–903	Milibis (glycobiarsol) Tablets	Sanofi Pharmaceuticals, Inc., 90 Park Ave., New York, NY 10016.
NDA 7–542	Tromexan Tablets	Novartis Pharmaceuticals Corp., 59 Route 10, East Hanover, NJ 07936–1080.
NDA 8–153	Dramamine (dimenhydrinate) Injection	G.D. Searle & Co., 4901 Searle Pkwy., Skokie, IL 60077.
NDA 8–843	Pro-Banthine (propantheline bromide) Injection	Do.
NDA 10–126	VapoSteam	Richardson-Vicks, 1 Far Mill Crossing, Shelton, CT 06484.
NDA 11–316	Temaril (trimeprazine tartrate) Tablets, Syrup, and Capsules	Allergan, 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92623–9534.
NDA 11–583	Hydeltrasol Injection	Merck & Co., Inc.
NDA 12–575	Actifed with Codeine (pseudoephedrine hydro-chloride, 30 milligrams (mg)/5 milliliters (mL), triprolidine hydrochloride, 25 mg/5 mL, codeine phosphate, 10 mg/5 mL)	Glaxo Wellcome Inc. 5 Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709.
NDA 13–553	Esimil (guanethidine monosulfate/hydro-chlorothiazide) Combination Tablets	Novartis Pharmaceuticals Corp.
NDA 15–865	Levoprome (methotrimeprazine) Injection	Immunex Corp., 51 University St., Seattle, WA 98101–2936.
NDA 16–349	10% Dextrose Injection	Baxter Healthcare Corp., Rte. 120 and Wilson Rd., Round Lake, IL 60073–0490.
NDA 16–717	10% Travert (invert sugar) Injection in PL 146 Container	Do.
NDA 16–938	Catarase (chymotrypsin intraocular solution) 1:5000 Ophthalmic Intraocular Solution	Ciba Vision Ophthalmics, 11460 John Creek Pkwy., Duluth, GA 30097–1556.
NDA 17–796	Byrel (piperazine citrate) Syrup	Sanofi Pharmaceuticals, Inc.

Application No.	Drug	Applicant
NDA 17–916	Stannous Macro-aggregated Albumin (SnMAA)	Syncor Pharmaceuticals, Inc., 1313 Washington Ave., Golden, CO 80401.
NDA 17–954	Bretylol (bretylium tosylate) Injection, 50 mg/mL	Faulding Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
NDA 18–115	Triaminic-12 (phenyl-propanolamine hydro-chloride 75 mg and chlorpheniramine maleate 12 mg) Sustained-release Tablets	Novartis Consumer Health, Inc., 560 Morris Ave., Summit, NJ 07901–1312.
NDA 18–193	Velosulin (Regular purified pork insulin) Injection	Novo Nordisk Pharmaceuticals Inc., 100 Overlook Ctr., suite 200, Princeton, NJ 08540–7810.
NDA 18–194	Insulatard (NPH purified pork isophane insulin suspension) Injection	Do.
NDA 18–195	Mixtard 70/30 (70% purified pork isophane suspension and 30% purified pork insulin) Injection	Do.
NDA 18–580	Yutopar (ritodrine hydrochloride) Injection	Astra USA Inc., P.O. Box 4500, Westborough, MA 01581–4500.
NDA 18–698	Thallous Chloride TL–201 Injection	Syncor Pharmaceuticals, Inc.
NDA 18935	Pseudoephedrine Hydrochloride 120 mg/Chlorpheniramine Maleate 12 mg Extended-release Capsules	Schwarz Pharma, P.O. Box 2038, Milwaukee, WI 53201.
NDA 19–381	Ten-K Tablets (Potassium Chloride Extended-release Tablets USP)	Novartis Pharmaceuticals Corp.
NDA 19–580	Osmovist (iotrolan) Injection	Berlex Laboratories, Inc., 340 Changebridge Rd., P.O. Box 1000, Montville, NJ 07450–1000.
NDA 19–585	Mixtard Human 70/30 (70% human insulin isophane suspension and 30% human insulin (semisynthetic)) Injection	Novo Nordisk Pharmaceuticals Inc.
NDA 20–755	Caverject (alprostadil injection) aqueous, 5 microgram (mcg)/mL (only those portions of NDA that deal with 5 mcg/mL strength)	Pharmacia & Upjohn, 7000 Portage Rd., Kalamazoo, MI 49001–0199.
NDA 50–031	RONDOMYCIN (methacycline hydrochloride) Syrup	Pfizer Inc., 235 East 42d St., New York, NY 10017–5755.
NDA 50–073	Coly-Mycin M Diagnostic (sodium colistimethate for diagnostic use)	Parke-Davis Pharmaceutical Research, 2800 Plymouth Rd., Ann Arbor, MI 48105.
NDA 50–075	Polycillin (ampicillin trihydrate)	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 50–287	TERRAMYCIN (oxytetra-cycline) Tablets	Pfizer Inc.
ANDA 40–097	Hydrocortisone and Acetic Acid Otic Solution USP, 1%/2%	Bausch & Lomb Pharmaceuticals, Inc., 8500 Hidden River Pkwy., Tampa, FL 33637.
ANDA 63–163	Clindamycin Phosphate Injection USP, 150 mg/mL)	Bedford Laboratories, Div. of Ben Venue Laboratories, Inc., 270 Northfield Rd., Bedford, OH 44146.
ANDA 70–107	PROPACET 100 (Propoxyphene Napsylate and Acetaminophen Tablets USP), 100 mg/650 mg	Teva Pharmaceuticals USA, 1510 Delp Dr., Kulpsville, PA 19443.
ANDA 70–691	Methyldopate Hydrochloride Injection USP, 50 mg/mL	Faulding Pharmaceutical Co., 11 Commerce Dr., Cranford, NJ 07016.
ANDA 70–732	Propoxyphene Napsylate and Acetaminophen Tablets USP, 100 mg/650 mg	Teva Pharmaceuticals USA Do.
ANDA 70–849	Methyldopate Hydrochloride Injection USP, 50 mg/mL	Faulding Pharmaceutical Co.
ANDA 70–969	Thiothixene Hydrochloride Oral Solution USP (Concentrate) 5 mg/mL	Alpharma, U.S. Pharmaceuticals Div., 333 Cassell Dr., suite 3500, Baltimore, MD 21224.
ANDA 71–990	Metoclopramide Injection USP, 5 mg/mL	Faulding Pharmaceutical Co.
ANDA 72–155	Metoclopramide Injection USP, 5 mg/mL	Bedford Laboratories.
ANDA 72–244	Metoclopramide Injection USP, 5 mg/mL	Do.
ANDA 72–247	Metoclopramide Injection USP, 5 mg/mL	Do.
ANDA 72–383	Sulfamethoxazole and Trimethoprim for Injection Concentrate USP	Do.
ANDA 72–427	Potassium Chloride Extended-release Capsules USP, 10 milliequivalents (mEq)	Savage Laboratories, 60 Baylis Rd., Melville, NY 11747.
ANDA 72–966	Albuterol Sulfate Tablets USP, 2 mg	Copley Pharmaceutical, Inc., 25 John Rd., Canton, MA 02021.
ANDA 72–967	Albuterol Sulfate Tablets USP, 4 mg	Do.
ANDA 73–307	Albuterol Sulfate Inhalation Solution, 0.5%	Do.
ANDA 73–398	Potassium Chloride Extended-release Capsules USP, 8 mEq	Savage Laboratories Do.
ANDA 73–495	Albuterol Sulfate Inhalation Solution, 0.083%	Copley Pharmaceutical, Inc.
ANDA 74–285	Diflunisal Tablets USP, 250 mg and 500 mg	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
ANDA 74–406	Sufentanil Citrate Injection USP, 50 mcg/mL	Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043–4705.
ANDA 74–665	Inapamide Tablets USP, 1.25 mg and 2.5 mg	Novopharm N.C. Inc., U.S. Agent for Novopharm Ltd., 4700 Novopharm Blvd., Wilson, NC 27893.
ANDA 80–763	Hydramine (diphenhydramine hydrochloride) Elixir 12.5 mg/5 mL	Alpharma.
ANDA 83–296	Aeroseb-DEX (dexamethasone 0.01%) Topical Aerosol Spray	Allergan Herbert, P.O. Box 19534, Irvine, CA 92623–9534.
ANDA 84–055	ELDECORT (Hydro-cortisone Cream USP) 2.5%	ICN Pharmaceuticals, Inc., 3300 Hyland Ave., Costa Mesa, CA 92626.
ANDA 85–482	LIBRITABS (Chlordiazepoxide Tablets USP)	Do.

Application No.	Drug	Applicant
ANDA 85–805	Aeroseb-HC (hydrocortisone 0.5%) Topical Aerosol Spray	Allergan Herbert.
ANDA 86–164	Nitrol Ointment (Nitroglycerin Ointment, 2%)	Savage Laboratories.
ANDA 86–604	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 5 mg	Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731.
ANDA 87–171	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 2.5 mg	Do.
ANDA 87–286	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 1 mg	Do.
ANDA 87–322	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 1.5 mg	Do.
ANDA 87–323	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 2 mg	Do.
ANDA 87–615	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 3 mg	Do.
ANDA 87–782	Nitrol Ointment (Nitroglycerin Ointment, 2% unit-dose)	Savage Laboratories.
ANDA 87–998	Spironolactone Tablets USP, 25 mg	Purepac Pharmaceutical Co.
ANDA 88–421	Amitriptyline Hydro-chloride Tablets USP, 10 mg	Copley Pharmaceutical Inc.
ANDA 88–422	Amitriptyline Hydro-chloride Tablets USP, 25 mg	Do.
ANDA 88–423	Amitriptyline Hydro-chloride Tablets USP, 50 mg	Do.
ANDA 88–424	Amitriptyline Hydro-chloride Tablets USP, 75 mg	Do.
ANDA 88–425	Amitriptyline Hydro-chloride Tablets USP, 100 mg	Do.
ANDA 88–426	Amitriptyline Hydro-chloride Tablets USP, 150 mg	Do.
ANDA 89–817	DEY-LUTE (Isoetharine Inhalation Solution USP) Sulfite-Free, 0.08%	Dey, L.P., 2751 Napa Valley Corporate Dr., Napa, CA 94558.
ANDA 89–818	DEY-LUTE (Isoetharine Inhalation Solution USP) Sulfite-Free, 0.1%	Do.
ANDA 89–819	DEY-LUTE (Isoetharine Inhalation Solution USP) Sulfite-Free, 0.17%	Do.
ANDA 89–820	DEY-LUTE (Isoetharine Inhalation Solution USP) Sulfite-Free, 0.25%	Do.
ANDA 89–932	Theophylline Extended-Release Capsules, 300 mg	F.H. Faulding & Co., Ltd., U.S. Agent: Faulding Inc., 200 Elmora Ave., Elizabeth, NJ 07207.
ANDA 89–976	Theophylline Extended-Release Capsules, 100 mg	Do.
ANDA 89–977	Theophylline Extended-Release Capsules, 200 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 July 12, 1999.

Dated: May 24, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–14656 Filed 6–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0046]

Annual Comprehensive List of Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing an annual comprehensive list of all guidance documents currently in use at the agency. FDA committed to publishing this list in its February 1997 ''Good Guidance Practices'' (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to inform the public of the existence and availability of all current guidance documents.

DATES: General comments on this list and on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Information on where to obtain a single copy of listed guidance documents is provided for each agency Center individually in the specific Center's list of guidance documents.

FOR FURTHER INFORMATION CONTACT: Lisa M. Helmanis, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its GGP's, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. The agency adopted the GGP's to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of such guidance.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the agency committed to publish an annual comprehensive list of guidance documents and quarterly updates that list all guidance documents that were issued and withdrawn during that quarter, including ''Level 2'' guidance documents.

On June 1, 1998, the President instructed all Federal agencies to ensure the use of ''plain language'' in all new documents. As part of this initiative,