Mineral Density: Results from the Post-Menopausal Estrogens/Progestins Intervention (PEPI) Trial,'' *Journal of the American Medical Association,* Vol 276, No. 17, pp. 1389–1396, November 6, 1996.

97. Harris, S. T., H. K. Genant, D. J. Baylink, et al., ''The Effects of Estrone (Ogen) on Spinal Bone Density of Postmenopausal Women,'' *Archives of Internal Medicine,* 151:1980–1984, October 1991.

98. United States Pharmacopeia 23, ''Conjugated Estrogens Monograph,'' p. 629, 1995.

99. Duursma, S. A., M. de Raadt, J. A. Raymakers, and A. A. Haspels, ''Is 1 mg of Estradiol Valerate or 0.625 mg of Conjugated Estrogens Sufficient for All Women to Prevent Menopausal Bone Loss?'' *Gynecological Endocrinology.,* 6:205–209, 1992.

100. Transcript and Summary Minutes of the meeting of FDA's Fertility and Maternal Health Drugs Advisory Committee, Vol. II, pp. 85–105, July 27–28, 1995.

101. Lafferty, F. W., and M. E. Fiske, ''Postmenopausal Estrogen Replacement: A Long-Term Cohort Study,'' *American Journal of Medicine,* 97:66–77, 1994.

102. Bhavnani, B. R., ''The Saga of the Ring B Unsaturated Equine Estrogens,'' *Endocrine Reviews,* 9:396–416, 1988.

103. Wyeth-Ayerst submission to the docket 94P–0429 (SUP 4), ''Contributions of Δ 8,9-dehydroestrone (Δ 8,9 DHES) to the Biologic Activities of Conjugated Estrogens,'' GTR–26521, pp. 38–40, September 25, 1995.,

104. Duramed submission to the docket 94P–0429 (C 94), January 8, 1997.

105. FDA, Center for Drug Evaluation and Research, Office of Clinical Pharmacology and Biopharmaceutics, Division of Pharmaceutical Evaluation II, ''A Pharmacokinetic Analysis of Conjugated Estrogens Including Δ 8,9-Dehydroestrone and 17Δ 8,9-Dehydroestradiol,'' October 25, 1996 (OCPB Report), Addendum 2, p. 26, March 31, 1997.

106. Id., p. 8, Table 5.

V. Notice of Opportunity for a Hearing

The Director of CDER (the Director) has evaluated the information discussed above and, on the grounds stated, is proposing to refuse to approve ANDA 40–115 and ANDA 40–154.

Therefore, notice is given to Duramed and Barr and to all other interested persons that under section 505 (j)(3)(C)(ii), (j)(3)(F), and (j)(3)(J) of the act and § 314.127 (a)(3)(ii), (a)(6), and (a)(12), the Director proposes to refuse to approve ANDA 40–115 and ANDA 40–154.

In accordance with section 505(j)(4)(C) of the act and § 314.200(a), the applicants are hereby given notice of an opportunity for a hearing to show that approval of ANDA 40–115 and ANDA 40–154 should not be refused.

An applicant who decides to seek a hearing shall file: (1) On or before September 8, 1997: a written notice of appearance and request for hearing, and (2) on or before October 6, 1997, the data, information, and analyses relied on to demonstrate that there is a genuine issue of material fact to justify a hearing, as specified in § 314.200(c). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of the applicant to file a timely written notice of appearance and request for a hearing, as required by § 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the proposed action, and a waiver of any contentions concerning the legal status of the referenced drug products.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact that precludes the refusal to approve the application, or when a request for a hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 505) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: July 29, 1997.

Murray M. Lumpkin,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–20792 Filed 8–6–97; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0326]

Sterling Drug, Inc., et al.; Withdrawal of Approval of 28 New Drug Applications, 9 Abbreviated Antibiotic Applications, and 46 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 28 new drug applications (NDA's), 9 abbreviated antibiotic applications (AADA's), and 46 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: September 8, 1997.

FOR FURTHER INFORMATION CONTACT: Olivia A. Vieira, 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 6–801	Neocurtasal	Sterling Drug, Inc., 90 Park Ave., New York, NY 10016.
NDA 8–472	Cyclaine	Merck & Co., Inc., P.O. Box 4, BLA–20, West Point, PA 19486.
NDA 8–656	Hydrocortone Acetate Topical Ointment	Do.

Application No.	Drug	Applicant
NDA 9–241	Serfia Tablets	Westerfield Pharma, 3941 Brotherton Rd., Cincinnati, OH 45209.
NDA 9–272	Evraserp Tablets	Evron Indust., 7475 North Rogers Ave., Chicago, IL 60626.
NDA 9–443	Rauwolfia Serpentina Tablets	Direct Laboratories, 377 Genesse St., Buffalo, NY 14204.
NDA 9–459	Hexamethonium Chloride Tablets	Global Pharms, 3725 Castor Ave., Philadelphia, PA 19124.
NDA 9–599	Sustac (Nitroglycerin) Extended-release Tablets, 2.6 milligrams (mg) and 6.5 mg	Key Pharms, 909 Third Ave., New York, NY 10022–4731.
NDA 9–720	Reserpine Tablets	S. F. Durst & Co., Inc., 1683 Winchester Rd., Philadelphia, PA 19020.
NDA 9–765	Reserpine Tablets	Hance Brothers & White Co., 12th & Hamilton Sts., Philadelphia, PA 19123.
NDA 9–812	Reserpine Tablets	Boyle & Co., 6330 Chalet Dr., Los Angeles, CA 90022.
NDA 9–926	Rauserpin Tablets	Ferndale Laboratories, Inc., 780 West Eight Mile Rd., Ferndale, MI 48220.
NDA 10–260	Ecolid Chloride	Novartis Pharms, 556 Morris Ave., Summit, NJ 07901.
NDA 10–408	Ekans Tablets 100 mg	Haag, Inc., 5 South 15th St., Richmond, VA 23219.
NDA 10–576	Perivas Tablets	Grant Chemical Co., Inc., 924 Rogers Ave., Brooklyn, NY 11226.
NDA 10–581	Hyserpin Tablets	Phys Products, 50 Washington St., Norwalk, CT 06856.
NDA 10–632	Serpena Tablets 0.25 mg (Reserpine)	Haag, Inc.
NDA 10–751	Reserpine Tablets	Horton & Converse Laboratories, Inc., 2200 South Figueroa St., Los Angeles, CA 90007.
NDA 10–883	Serpanray Injection	Panray, P.O. Box 150, Englewood, NJ 07631.
NDA 12–128	Fovane (benzthiazide) Tablets	Pfizer, 235 East 42d St., New York, NY 10017–5755.
NDA 12–285	Syntocinon (oxytocin nasal solution) Nasal Spray	Novartis Pharmaceutical Corp., 59 Rte. 10, East Hanover, NJ 07936–1080.
NDA 12–911	Metopirone (metyrapone USP) Tablets (only those portions of NDA that deal with Tablets)	Novartis Pharms.
NDA 12–985	Duphaston (Dydrogesterone) Tablets, 5, 10, and 20 mg	Solvay Pharmaceuticals, 901 Sawyer Rd., Marietta, GA 30062.
NDA 13–412	CUEMID	Merck & Co., Inc.
NDA 13–538	Decaderm	Do.
NDA 17–926	Regular Insulin (insulin injection, USP (Pork))	Novo Nordisk Pharmaceuticals, Inc., Suite 200, 100 Overlook Center, Princeton, NJ 08540–7810.
NDA 17–929	NPH Insulin (isophane insulin suspension, USP (Beef))	Do.
NDA 17–998	Lente Insulin (insulin zinc suspension, USP (Beef))	Do.
AADA 60–633	Tetracycline Syrup, 125 mg/5 milliliters (mL)	Alpharma, U.S. Pharmaceuticals Div., Suite 3500, 3333 Cassell Dr., Baltimore, MD 21224.
AADA 60–730	Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution, USP	Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043–4705.
AADA 61–450	Oxacillin Sodium Capsules, USP	Apothecon, Inc., P.O. Box 4500, Princeton, NJ 08543–4500.
AADA 62–300	Tetracycline Hydrochloride Capsules USP, 250 mg and 500 mg	Warner Chilcott, Inc., Rockaway 80 Corp. Center, 100 Enterprise Dr., Suite 280, Rockaway, NJ 07866.
AADA 62–521	Neomycin and Polymyxin B Sulfates and Hyrocortisone Otic Suspension, USP	Steris Laboratories, Inc.
AADA 62–625	Ampicillin Trihydrate Non-Sterile Bulk	SmithKline Beecham Pharmaceuticals, 1250 South Collegeville Rd., P.O. Box 5089, Collegeville, PA 19426–0989.
AADA 62–724	Cefadyl (Sterile Cephapirin Sodium, USP), ADD-Vantage vials	Apothecon, Inc.
AADA 62–973	Cephalexin Capsules USP, 250 mg	Do.
AADA 62–974	Cephalexin Capsules USP, 500 mg	Do.
ANDA 70–042	Metronidazole Injection USP, 5 mg/mL	Steris Laboratories, Inc.
ANDA 70–452	Methyldopa Tablets, USP, 500 mg	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
ANDA 70–749	Methyldopa Tablets, USP, 125 mg	Do.
ANDA 70–750	Methyldopa Tablets, USP, 250 mg	Do.
ANDA 70–912	Diazepam Injection USP, 5 mg/mL	Steris Laboratories, Inc.
ANDA 71–122	Ibuprofen Tablets, USP, (200 mg, orange)	Purepac Pharmaceutical Co.
ANDA 71–455	Pseudoephedrine Hydrochloride and Chlorpheniramine Maleate Extended-Release Capsules, 120 mg/12 mg	KV Pharmaceutical Co., 2503 South Hanley Rd., St. Louis, MO 63144–2555.
ANDA 71–656	Metaproterenol Sulfate Syrup USP, (10 mg/5 mL)	Morton Grove Pharmaceuticals, Inc., 6451 West Main St., Morton Grove, IL 60053.
ANDA 71–664	Ibuprofen Tablets, USP, (200 mg, white)	Purepac Pharmaceutical Co.
ANDA 71–964	Ibuprofen Tablets, USP, 800 mg	Do.
ANDA 72–758	Triprolidine and Pseudoephedrine Hydrochlorides Extended-Release Caplets, 5 mg/120 mg	KV Pharmaceutical Co.
ANDA 80–325	Prednisolone Tablets, 5 mg	Purepac Pharmaceutical Co.
ANDA 80–753	Reserpine Tablets USP, 0.1 mg and 0.25 mg	Do.
ANDA 83–013	Cyanocobalamin Injection USP, 100 micrograms (μg)/mL	Steris Laboratories, Inc.
ANDA 83–064	Cyanocobalamin Injection USP, 1,000 μg/mL	Do.
ANDA 83–120	Cyanocobalamin Injection USP, 100 μg/mL and 1,000 μg/mL	Do.
ANDA 83–532	Promethazine Hydrochloride Injection USP, 50 mg/mL	Do.

Application No.	Drug	Applicant
ANDA 83–533	Diphenhydramine Hydrochloride Injection USP, 10 mg/mL	Do.
ANDA 83–534	Thiamine Hydrochloride Injection USP, 100 mg/mL and 200 mg/mL	Do.
ANDA 83–535	Procaine Hydrochloride Injection USP, 1% and 2%	Do.
ANDA 83–595	Testosterone Propionate Injection USP, 100 mg/mL	Do.
ANDA 83–627	Lidocaine Hydrochloride Injection USP, 1% and 2%	Do.
ANDA 83–654	Sterile Prednisolone Acetate Suspension USP, 25 mg/mL	Do.
ANDA 83–667	Testosterone Enanthate Injection USP, 100 mg/mL and 200 mg/mL	Do.
ANDA 83–759	Sterile Hydrocortisone Acetate Sterile Suspension USP, 25 mg/mL and 50 mg/mL	Do.
ANDA 83–760	Pyridoxine Hydrochloride Injection USP, 100 mg/mL	Do.
ANDA 84–355	Dexamethasone Sodium Phosphate Injection USP, 4 mg/mL (base)	Do.
ANDA 84–401	Testosterone Cypionate Injection USP, 100 mg/mL and 200 mg/mL	Do.
ANDA 84–740	Phendimetrazine Tartrate Tablets, 35 mg (Gray)	Inwood Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731.
ANDA 84–741	Phendimetrazine Tartrate Tablets, 35 mg (Yellow)	Do.
ANDA 84–742	Phendimetrazine Tartrate Tablets, 35 mg (Pink)	Do.
ANDA 84–743	Phendimetrazine Tartrate Tablets, 35 mg (Green)	Do.
ANDA 85–374	Sterile Methylprednisolone Acetate Sterile Suspension USP, 40 mg/mL	Steris Laboratories, Inc.
ANDA 85–463	Lidocaine Hydrochloride and Epinephrine Injection USP 1%; 0.01 mg/mL	Do.
ANDA 85–528	Hydroxocobalamin Injection USP, 1,000 µg/mL	Do.
ANDA 85–529	Sterile Triamcinolone Diacetate Suspension USP, 40 mg/mL	Do.
ANDA 85–781	Sterile Prednisolone Acetate Suspension USP, 50 mg/mL	Do.
ANDA 86–052	Hydrocortisone Acetate Cream, 1%	Purepac Pharmaceutical Co.
ANDA 86–507	Sterile Methylprednisolone Acetate Suspension USP, 80 mg/mL	Steris Laboratories, Inc.
ANDA 87–192	Triamcinolone Acetonide Lotion USP, 1%	Alpharma, U.S. Pharmaceuticals Div.
ANDA 87–214	Phendimetrazine (Extended-release Capsules, 105 mg)	D. M. Graham Laboratories, Inc., 58 Pearl St., P.O. Box P, Hobart, NY 13788.
ANDA 87–248	Sterile Methylprednisolone Acetate Suspension USP, 20 mg/mL	Steris Laboratories, Inc.
ANDA 87–598	Nandrolone Decanoate Injection USP, 50 mg/mL	Do.
ANDA 87–599	Nandrolone Decanoate Injection USP, 100 mg/mL	Do.
ANDA 88–062	Hyrex-105 (Phendimetrazine Tartrate Extended-release Capsules, 105 mg)	D. M. Graham Laboratories, Inc.
ANDA 88–305	Axotal Tablets (Butalbital and Aspirin Tablets USP) 50 mg/650 mg	Savage Laboratories, 60 Baylis Rd., Melville, NY 11747.

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 8, 1997.

Dated: July 17, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–20871 Filed 8–6–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Grantee Reporting Requirements for the Rural Health Network Grant Program—New—

The Rural Health Network Grant Program is authorized by Section 330A of the Public Health Service Act as amended by the Health Centers Consolidation Act of 1996 (Public Law 104–229). The purpose of the program is to assist in the development of vertically integrated networks of health care providers in rural communities. Grantees will be working to change the delivery system in their service areas and will be using the federal funds to develop network capabilities.

Grantees will be asked to submit a baseline report and semiannual tracking reports which provide information on progress towards goals and objectives of the network, progress toward developing the governance and organizational arrangements for the network, specific network activities,