CONTACT PERSON FOR MORE INFORMATION: Joseph R. Coyne, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.bog.frb.fed.us for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: May 8, 1998.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 98–12656 Filed 5–8–98; 12:29 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pfizer, Inc.; Withdrawal of Approval of NADA's

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new animal drug applications (NADA's) held by Pfizer, Inc. The NADA's provide for use of oxytetracycline hydrochloride. The sponsor requested the withdrawal of approval of the NADA's because the animal drug products are no longer manufactured or marketed.

EFFECTIVE DATE: May 12, 1998.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017 is the sponsor of NADA 8–696 TM–5 Antibiotic Feed Supplement (oxytetracycline), NADA 10–661 Terramycin Egg Formula (oxytetracycline hydrochloride), NADA 11–034 Liquimast Solution for Mastitis (oxytetracycline hydrochloride), and NADA 13–470 TM–10 Premix (oxytetracycline). The animal drug products were subject to review under the National Academy of Sciences/National Research Council, Drug Efficacy Study Implementation Program, and are currently subject to requirements for finalization under that program. Pfizer, Inc., the current sponsor, requested withdrawal of approval of the NADA's because the animal drug products are no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.48), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approvals of NADA's 8–696, 10–661, 11–034, 13–470, and all supplements and amendments thereto are hereby withdrawn, effective May 22, 1998.

These products had not been the subject of a regulation published under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b). Therefore, an amendment to the animal drug regulations to reflect the withdrawal of approvals is not required.

Dated: April 24, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–12612 Filed 5–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0285]

Sanofi Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 21 New Drug Applications and 62 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 21 new drug applications (NDA's) and 62 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: June 11, 1998.

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 4–496	Pipanol Powder and Tablets (trihyphenidyl)	Sanofi Pharmaceuticals, Inc., 90 Park Ave., New York, NY 10016.
NDA 6–328	Isuprel (isoproterenol hydrochloride) Sublingual Tablets, 10 milligrams (mg) and 15 mg	Do.
NDA 7–514	Insulin, NPH Iletin	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
NDA 8–256	Insulin	Do.
NDA 8–717	Acetaminophen Tablets USP (acetaminophen tablets)	Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216–6532.
NDA 8–847	Sucostrin (succinylcholine chloride injection)	Apothecon, Inc., P.O. Box 4500, Princeton, NJ 08543–4500.
NDA 8–983	Arfonad (trimethaphan camsylate) Ampules	Hoffmann-La Roche, Inc., 40 Kingsland St., Nutley, NJ 07110–1199.
NDA 9–088	Neothylline (dyphylline) injection	TEVA Pharmaceuticals USA (formerly Lemmon Co.), 650 Cathill Rd., Sellersvile, PA 18960.
NDA 9–300	Insulin, Lente Iletin I	Eli Lilly and Co.
NDA 9–410	Lotusate Tablets and and Capsules (talbutal)	Sanofi Pharmaceuticals, Inc.
NDA 9–479	Jayne's Liquid Vermifuge (piperazine hexahydrate)	Do.

Application No.	Drug	Applicant
NDA 10–966	Insulin, Ultralente	Eli Lilly and Co.
NDA 10–967	Insulin, Semilente	Do.
NDA 11–446	Sterane (prednisolone acetate injection) Intramuscular and Intra-Articular	Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755.
NDA 11–724	Fenarol Tablets (chlormezanone)	Sanofi Pharmaceuticals, Inc.
NDA 17–108	Methadone HydrochlorideTablets, 2.5 mg, 5 mg, 10 mg, and 40 mg	Eon Labs Manufacturing, Inc., 227–15 North Conduit Ave., Laurelton, NY 11413.
NDA 17–446	pHisoScrub (hexachlorophene)	Sanofi Pharmaceuticals, Inc.
NDA 18–217	Suprol (suprofen) Capsules, 200 mg	R. W. Johnson Pharmaceutical Research Institute, 920 Rt. 202 South, P.O. Box 300, Raritan, NJ 08869–0602.
NDA 18–660	10% Travamulsion (Intravenous Fat Emulsion)	Baxter Healthcare Corp., Rt. 120 and Wilson Rd., Round Lake, IL 60073.
NDA 18–719	Modrastane (trilostane) Capsules	Sanofi Pharmaceuticals, Inc.
NDA 19–358	Azo Gantrisin (sulfisoxazole and phenazopyridine hydrochloride) Tablets	Hoffman-La Roche, Inc.
ANDA 60–734	BACIGUENT Ophthalmic Ointment (Bacitracin Ophthalmic Ointment, USP)	Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199.
ANDA 62–036	Aerosporin (Polymyxin B Sulfate Sterile Powder)	Glaxo Wellcome, Inc., Five Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709.
ANDA 62–363	Cleocin T Topical Solution (Clindamycin Phosphate Topical Solution, USP)	Pharmacia & Upjohn Co.
ANDA 62–479	Doxycycline Hyclate Capsules USP, 50 mg and 100 mg (Base)	Purepac Pharmaceutical Co. 200 Elmora Ave., Elizabeth, NJ 07207.
ANDA 62–913	Clindamycin Phosphate Injection USP, 150 mg/milliliter (mL)	Marsam Pharmaceuticals, Inc., Bldg. 31, Olney Ave., P.O. Box 1022, Cherry Hill, NJ 08034.
ANDA 70–053	Betamethasone Valerate Cream USP, 0.1%	Clay-Park Labs, Inc., 1700 Bathgate Ave., Bronx, NY 10457.
ANDA 70–829	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/15 mg	Invamed, Inc., 2400 Rt. 130 North, Dayton, NJ 08810.
ANDA 70–830	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/25 mg	Do.
ANDA 70–850	Metoclopramide Tablets USP, 10 mg	Do.
ANDA 70–949	Metoclopramide Oral Solution USP, Eq. 5 mg Base/5 mL	Morton Grove Pharmaceuticals, Inc., 6451 West Main St., Morton Grove, IL 60053.
ANDA 71–071	Haloperidol Tablets USP, 0.5 mg	Purepac Pharmaceutical Co.
ANDA 71–072	Haloperidol Tablets USP, 1 mg	Do.
ANDA 71–073	Haloperidol Tablets USP, 2 mg	Do.
ANDA 71–074	Haloperidol Tablets USP, 5 mg	Do.
ANDA 71–075	Haloperidol Tablets USP, 10 mg	Do.
ANDA 71–076	Haloperidol Tablets USP, 20 mg	Do.
ANDA 71–658	Propranolol Hydrochloride Tablets USP, 10 mg	Invamed, Inc.
ANDA 71–687	Propranolol Hydrochloride Tablets USP, 20 mg	Do.
ANDA 71–688	Propranolol Hydrochloride Tablets USP, 40 mg	Do.
ANDA 71–689	Propranolol Hydrochloride Tablets USP, 80 mg	Do.
ANDA 71–811	Naloxone Hydrochloride Injection USP, 0.4 mg/mL	Marsam Pharmaceuticals, Inc.
ANDA 71–812	Methyldopate Hydrochloride Injection USP, 50 mg/mL	Do.
ANDA 71–938	Ibuprofen Tablets USP, 800 mg	Invamed, Inc.
ANDA 72–064	Ibuprofen Tablets USP, 400 mg	Do.
ANDA 72–065	Ibuprofen Tablets USP, 600 mg	Do.
ANDA 72–109	Doxepin Hydrochloride Capsules, 25 mg	Purepac Pharmaceutical Co.
ANDA 72–197	Propranolol Hydrochloride Tablets USP, 60 mg	Invamed, Inc.
ANDA 72–198	Propranolol Hydrochloride Tablets USP, 90 mg	Do.
ANDA 72–233	Verapamil Hydrochloride Injection USP, 2.5 mg/mL (ampuls)	Marsam Pharmaceuticals, Inc.
ANDA 72–371	Diazepam Injection USP, 5 mg/mL, 2 mL (ampul)	Do.
ANDA 72–436	Metoclopramide Tablets USP, 5 mg	Invamed, Inc.
ANDA 72–516	Haloperidol Injection USP, 5 mg/mL, 1 mL (ampul)	Marsam Pharmaceuticals, Inc.
ANDA 72–517	Haloperidol Injection USP, 5 mg/mL, 10 mL (vial)	Do.
ANDA 73–054	Doxepin Hydrochloride Capsules, 10 mg	Purepac Pharmaceutical Co.
ANDA 73–055	Doxepin Hydrochloride Capsules, 50 mg	Do.
ANDA 73–098	PEG–Lyte (PEG 3350 and Electrolytes for Oral Solution USP)	Invamed, Inc.
ANDA 73–485	Verapamil Hydrochloride Injection USP, 2.5 mg/mL (vials)	Marsam Pharmaceuticals, Inc.
ANDA 74–125	Pindolol Tablets USP, 5 mg and 10 mg	Purepac Pharmaceutical Co.
ANDA 74–302	Albuterol Sulfate Syrup, 2 mg (base)/5 mL	Mova Pharmaceutical Corp., P.O. Box 8639, Caguas, PR 00726.
ANDA 74–510	Etoposide Injection 20 mg/mL, 50 mL Pharmacy Bulk Package	Gensia Laboratories, 19 Hughes, Irvine, CA 92718–1902.
ANDA 81–222	ADRUCIL (Flourouracil Injection, USP) 500 mg/10 mL Ampuls	Pharmacia & Upjohn Co.

Application No.	Drug	Applicant
ANDA 81–242	FOLEX PFS (Methotrexate Sodium Injection, USP) 25 mg/mL	Do.
ANDA 83–187	Afaxin (brand of vitamin A Palmitate)	Sanofi Pharmaceuticals, Inc.
ANDA 83–237	Diphenhydarmine Hydrochloride Elixir USP	Purepac Pharmaceutical Co.
ANDA 83–278	Propoxyphene Hydrochloride Capsules USP, 65 mg	Do.
ANDA 83–856	ESTRATAB (Esterified Estrogens Tablets, USP) 1.25 mg	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
ANDA 83–921	Elixophyllin (Theophylline Soft Gelatin Capsules, 200 mg)	Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731.
ANDA 84–003	Quinidine Sulfate Tablets USP, 200 mg	Purepac Pharmaceutical Co.
ANDA 85–545	Elixophyllin (Theophylline Soft Gelatin Capsules, 100 mg)	Forest Laboratories, Inc.
ANDA 86–826	Elixophyllin SR (Theophylline Extended-Release Capsules, USP) 125 mg and 250 mg	Do.
ANDA 87–999	Spironolactone and Hydrochlorothiazide Tablets USP, 25 mg/25 mg	Purepac Pharmaceutical Co.
ANDA 89–284	Procainamide Hydrochloride Extended-Release Tablets USP, 500 mg	Invamed, Inc.
ANDA 89–463	Promethazine Hydrochloride Injection USP, 25 mg/mL	Marsam Pharmaceuticals, Inc.
ANDA 89–477	Promethazine Hycrochloride Injection USP, 50 mg/mL	Do.
ANDA 89–501	Phenytoin Sodium Injection USP, 50 mg/mL, 2 mL (ampul)	Do.
ANDA 89–511	Codaphen (Acetaminophen and Codeine Phosphate Tablets USP) 500 mg/15 mg	Roxane Laboratories, Inc.
ANDA 89–512	Codaphen (Acetaminophen and Codeine Phosphate Tablets USP) 500 mg/30 mg	Do.
ANDA 89–513	Codaphen (Acetaminophen and Codeine Phosphate Tablets USP) 500 mg/60 mg	Do.
ANDA 89–563	Chlorpromazine Hydrochloride Injection USP, 25 mg/mL	Marsam Pharmaceuticals, Inc.
ANDA 89–675	Prochlorperazine Edisylate Injection USP, 5 mg/mL	Do.
ANDA 89–779	Phenytoin Sodium Injection USP, 50 mg/mL, 2 mL and 5 mL (vials)	Do.
ANDA 89–849	Methocarbamol Injection USP, 100 mg/mL	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 June 11, 1998.

Dated: April 28, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–12613 Filed 5–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0196]

Alltech Biotechnology Center; Filing of Food Additive Petition (Animal Use)-Selenium Yeast

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Alltech Biotechnology Center has filed a petition proposing that the food additive regulations be amended to provide for the safe use of selenium yeast as a source of selenium in animal feeds.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nelson S. Chou, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0161.

SUPPLEMENTARY INFORMATION: Under section 409 (b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 2238) has been filed by Alltech Biotechnology Center, 3031 Catnip Hill Pike, Nicholasville, KY 40356. The petition proposes to amend the food additive regulations in part 573 *Food Additives Permitted in the Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the safe use of selenium yeast as a source of selenium in animal feeds.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: April 24, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–12611 Filed 5–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96F–0341]

MacMillan Bloedel, Ltd.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.