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of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective June 11, 1998.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.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 6B4517) proposing that the food additive regulations be amended to provide for the safe use of diethylene glycol as a component of a pulp bleaching medium used in the manufacture of paper and paperboard intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 Ct. SW., Washington, DC 20204, 202–418–3095.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 30, 1996 (61 FR 51118), FDA announced that a food additive petition (FAP 6B4517) had been filed by MacMillan Bloedel, Ltd., c/o Camplong & Associates, Inc., P.O. Box 238, Schomberg, Ontario L0G 1T0, Canada. The filing notice stated that the petition proposed to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of diethylene glycol as a pulp bleaching agent for paper and paperboard intended for use in contact with food. Upon further review, FDA has determined that the petition proposed the use of diethylene glycol as a component of a pulp bleaching medium used in the manufacture of food-contact paper and paperboard. MacMillan Bloedel, Ltd. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: April 10, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–12541 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–0195]

Vanetta S.p.A.; Filing of Food Additive Petition (Animal Use) Menadione Nicotinamide Bisulfite

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Vanetta S.p.A. has filed a petition to allow the use of menadione nicotinamide bisulfite in swine diets as a source of vitamin K activity and niacin.

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: Michaela G. Alewynse, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6657.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) 21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 2239) has been filed by Vanetta S.p.A., Via Alzia Trento 10, Milano, Corsico, Italy. 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 use of menadione nicotinamide bisulfite in swine diets as a source of vitamin K activity and niacin.

The agency has determined under 21 CFR 25.32 that this action is of the 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. 98–12540 Filed 5–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food 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: Food 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 June 15 and 16, 1998, 8 a.m. to 6 p.m.; and June 17, 1998, 8 a.m. to 1 p.m..

Location: Sheraton Reston Hotel, Grand Ballroom, 11810 Sunrise Valley Dr., Reston, VA.

Contact: Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS–5), 202–205–4727, or Catherine M. DeRoever (HFS–22), 202–205–4251, FAX 202–205–4970, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will receive and undertake a scientific discussion about new data that have become available regarding the food additive olestra.

In the **Federal Register** of January 30, 1996 (61 FR 3118), FDA approved olestra for use as a food additive to replace conventional fats in prepackaged savory snacks. Olestra is a sucrose polyester formed with long chain fatty acids. The agency determined, based on its evaluation of the evidence in the record at that time, that there is a reasonable certainty that no harm will result from the use of olestra in savory snacks. At the time of approval, the petitioner, Proctor and Gamble Co. (P&G), agreed to perform additional studies of olestra exposure (both amounts consumed and patterns of consumption) and the effects of olestra consumption. P&G also agreed to provide FDA with access to all data and reports of those studies as such information became available. At the time of olestra's approval, FDA committed to review all data received from P&G's studies, as well as any other new data that bear on the safe use of this additive, and present such information to the committee within 30 months of the approval.

Committee discussion will focus on data gathered from passive surveillance of complaints attributed to olestra consumption; the active surveillance of populations consuming savory snacks, including olestra snacks; any additional new data that have become available that bear on the safety of olestra (such as data and information on the health significance of carotenoids); and various other studies submitted by P&G (e.g., rechallenge, home consumption, and acute consumption test). The committee will consider whether these newly developed data are consistent with the original safety decision or whether the new data contradict FDA's original determination that there is a reasonable certainty of no harm from the use of