

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of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective June 11, 1998.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

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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]

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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.