comments and suggestions submitted within 60 days of this publication.

Dated: November 25, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–31855 Filed 12–4–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0480]

Zenith Goldline Pharmaceuticals; Withdrawal of Approval of 11 Abbreviated Antibiotic Applications and 105 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 11 abbreviated antibiotic applications (AADA's) and 105 abbreviated new drug applications (ANDA's). Zenith Goldline Pharmaceuticals 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agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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: January 5, 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: Zenith Goldline Pharmaceuticals, 140 Legrand Ave., Northvale, NJ 07647, has informed FDA that the drug products listed in the following table are no longer marketed and has requested that FDA withdraw approval of the applications. Zenith Goldline Pharmaceuticals has also, by its request, waived its opportunity for a hearing.

Application No.	Drug
AADA 60–072	Penicillin G Potassium Powder, 100,000 units/5 milliliters (mL), 200,000 units/5 mL, 250,000 units/5 mL, 400,000 units/5 mL, 500,000 units/5 mL
AADA 60–073	Penicillin G Potassium Tablets USP, 100,000 units/Tab, 200,000 units/Tab, 250,000 units/Tab, 400,000 units/Tab, 500,000 units/Tab
AADA 60–104	Chlortetracycline Hydrochloride (HCl) Capsules USP, 250 milligrams (mg)
AADA 60–518	Penicillin V Potassium Tablets USP, 125 mg, 250 mg, 500 mg
AADA 60–519	Penicillin V Potassium Powder, 125 mg/5 mL, 250 mg/5 mL
AADA 60–692	Ampicillin Capsules USP (Trihydrate), 250 mg, 500 mg
AADA 60–765	Ampicillin Capsules USP (Trihydrate), 250 mg, 500 mg
AADA 61–183	Ampicillin for Oral Suspension USP, 125 mg/5 mL, 250 mg/5 mL
AADA 61–468	Tetracycline Syrup, 125 mg/5 mL
AADA 62–237	Erythromycin Estolate Capsules USP, 250 mg
AADA 62–762	Cephradine Capsules USP, 250 mg, 500 mg
ANDA 70–360	Diazepam Tablets USP, 2 mg
ANDA 70–361	Diazepam Tablets USP, 5 mg
ANDA 70–362	Diazepam Tablets USP, 10 mg
ANDA 70–935	Perphenazine and Amitriptyline HCl Tablets USP, 2 mg/10 mg
ANDA 70–936	Perphenazine and Amitriptyline HCl Tablets USP, 2 mg/25 mg
ANDA 70–937	Perphenazine and Amitriptyline HCl Tablets USP, 4 mg/10 mg
ANDA 70–938	Perphenazine and Amitriptyline HCl Tablets USP, 4 mg/25 mg
ANDA 70–939	Perphenazine and Amitriptyline HCl Tablets USP, 4 mg/50 mg
ANDA 71–154	Ibuprofen Tablets USP, 200 mg (Round)
ANDA 71–458	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/15 mg
ANDA 71–459	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/25 mg
ANDA 71–460	Methyldopa and Hydrochlorothiazide Tablets USP, 500 mg/30 mg
ANDA 71–461	Methyldopa and Hydrochlorothiazide Tablets USP, 500 mg/50 mg
ANDA 71–552	Propranolol HCl and Hydrochlorothiazide Tablets USP, 40 mg/25 mg
ANDA 71–553	Propranolol HCl and Hydrochlorothiazide Tablets USP, 80 mg/25 mg
ANDA 72–040	Ibuprofen Tablets USP, 200 mg (Caplet)
ANDA 72–063	Propranolol HCl Tablets USP, 10 mg
ANDA 72–066	Propranolol HCl Tablets USP, 20 mg
ANDA 72–067	Propranolol HCl Tablets USP, 40 mg
ANDA 72–068	Propranolol HCl Tablets USP, 60 mg
ANDA 72–069	Propranolol HCl Tablets USP, 80 mg
ANDA 80–078	Nitrofurantoin Tablets (Microcrystalline) 50 mg, 100 mg
ANDA 80–143	Trisulfapyrimidines Tablets USP
ANDA 80–215	Propylthiouracil Tablets USP, 50 mg
ANDA 80–270	Isoniazid Tablets USP, 100 mg
ANDA 80–283	Prednisone Tablets USP, 5 mg
ANDA 80–378	Prednisolone Tablets USP, 5 mg
ANDA 80–630	Cortisone Acetate Tablets USP, 25 mg
ANDA 80–735	Dimenhydrinate Tablets USP, 50 mg
ANDA 80–762	Diphenhydramine HCl Capsules USP, 25 mg, 50 mg
ANDA 80–779	Chlorphenirarnine Maleate Tablets USP, 4 mg
ANDA 83–035	Vitamin A Capsules USP, 50,000 units
ANDA 83–077	Propoxyphene Compound Capsules

Application No.	Drug
ANDA 83–180	Niacin Tablets USP, 500 mg
ANDA 83–190	Vitamin A Palmitate Capsules, 50,000 units
ANDA 83–416	Dexamethasone Tablets USP, 0.75 mg
ANDA 83–461	Pentobarbital Sodium Capsules USP, 50 mg, 100 mg
ANDA 83–484	Butabarbital Sodium Tablets USP, 15 mg
ANDA 83–536	Cortisone Acetate Tablets USP, 25 mg
ANDA 83–549	Chlorpromazine HCl Tablets USP, 10 mg, 25 mg, 50 mg
ANDA 83–568	Reserpine and Hydrochlorothiazide Tablets USP, 0.1 mg/50 mg
ANDA 83–570	Chlordiazepoxide HCl Capsules USP, 25 mg
ANDA 83–571	Reserpine and Hydrochlorothiazide Tablets USP, 0.125 mg/25 mg
ANDA 83–572	Reserpine and Hydrochlorothiazide Tablets USP, 0.1 mg/25 mg
ANDA 83–573	Reserpine and Hydrochlorothiazide Tablets USP, 0.125 mg/50 mg
ANDA 83–574	Chlorpromazine HCl Tablets USP, 100 mg
ANDA 83–575	Chlorpromazine HCl Tablets USP, 200 mg
ANDA 83–597	Propoxyphene HCl Capsules USP, 32 mg
ANDA 83–603	Promethazine HCl Tablets USP, 25 mg
ANDA 83–604	Promethazine HCl Tablets USP, 12.5 mg
ANDA 83–610	Isoniazid Tablets USP, 300 mg
ANDA 83–613	Promethazine HCl Tablets USP, 50 mg
ANDA 83–741	Chlordiazepoxide HCl Capsules USP, 5 mg
ANDA 83–742	Chlordiazepoxide HCl Capsules USP, 10 mg
ANDA 83–750	Triamcinolone Tablets USP, 4 mg
ANDA 83–784	Meclizine HCl Tablets USP, 12.5 mg
ANDA 83–876	Hydralazine HCl and Hydrochlorothiazide Tablets, 25 mg/15 mg
ANDA 83–877	Reserpine, Hydralazine HCl, and Hydrochlorothiazide Tablets USP, 0.1 mg/25 mg/15 mg
ANDA 84–040	Butabarbital Sodium Tablets USP, 30 mg
ANDA 84–133	Prednisone Tablets USP, 10 mg
ANDA 84–134	Prednisone Tablets USP, 20 mg
ANDA 84–181	Meprobamate Tablets USP, 600 mg
ANDA 84–291	Reserpine, Hydralazine HCl and Hydrochlorothiazide Tablets USP, 0.1 mg/25 mg/15 mg
ANDA 84–351	Brompheniramine Maleate Tablets USP, 4 mg
ANDA 84–437	Hydralazine HCl Tablets USP, 25 mg
ANDA 84–443	Hydralazine HCl Tablets USP, 10 mg
ANDA 84–469	Hydralazine HCl Tablets USP, 50 mg
ANDA 84–473	Isosorbide Dinitrate Sublingual Tablets USP, 2.5 mg
ANDA 84–474	Isosorbide Dinitrate Sublingual Tablets USP, 5 mg
ANDA 84–549	Quinidine Sulfate Tablets USP, 200 mg
ANDA 84–581	Hydralazine HCl Tablets USP, 100 mg
ANDA 84–648	Methocarbamol Tablets USP, 500 mg
ANDA 84–649	Methocarbamol Tablets USP, 750 mg
ANDA 84–658	Hydrochlorothiazide Tablets USP, 50 mg
ANDA 84–689	Bethanechol Chloride Tablets USP, 25 mg
ANDA 84–976	Meclizine HCl Tablets USP, 25 mg
ANDA 85–273	Triprolidine and Pseudoephedrine Hydrochlorides Tablets USP, 2.5 mg/60 mg
ANDA 85–441	Butalbital Compound Tablets USP, 50 mg/325 mg
ANDA 85–553	Phenterimine HCl Tablets, 8 mg
ANDA 85–611	Phendimetrazine Tartrate Tablets USP, 35 mg
ANDA 85–612	Phendimetrazine Tartrate Tablets USP, 35 mg
ANDA 85–682	Phendimetrazine Tartrate Tablets USP, 35 mg
ANDA 85–869	Secobarbital Sodium Capsules USP, 100 mg
ANDA 86–035	Isosorbide Dinitrate Tablets USP, 10 mg
ANDA 86–329	Phentermine HCl Capsules USP, 30 mg
ANDA 87–004	Spironolactone and Hydrochlorothiazide Tablets USP, 25 mg/25 mg
ANDA 87–008	Dipyridamole Tablets USP, 25 mg
ANDA 87–108	Spironolactone Tablets USP, 25 mg
ANDA 87–186	Ergoloid Mesylates Tablets USP (Sublingual), 0.5 mg
ANDA 87–216	Hydroxyzine HCl Tablets USP, 10 mg
ANDA 87–316	Dipyridamole Tablets USP, 50 mg
ANDA 87–320	Dipyridamole Tablets USP, 75 mg
ANDA 87–353	Chlorpropamide Tablets USP, 250 mg
ANDA 87–410	Hydroxyzine HCl Tablets USP, 25 mg
ANDA 87–411	Hydroxyzine HCl Tablets USP, 50 mg
ANDA 87–555	Chlorthalidone Tablets USP, 25 mg
ANDA 87–769	Sulfinpyrazone Tablets USP, 100 mg
ANDA 87–786	Methyclothiazine Tablets USP, 5 mg
ANDA 87–947	Chlorthalidone Tablets USP, 50 mg
ANDA 88–218	Phenylbutazone Capsules USP, 100 mg
ANDA 88–356	Hydralazine HCl and Hydrochlorothiazide Capsules, 25 mg/25 mg
ANDA 88–357	Hydralazine HCl and Hydrochlorothiazide Capsules, 50 mg/50 mg
ANDA 88–358	Hydralazine HCl and Hydrochlorothiazide Capsules, 100 mg/50 mg
ANDA 88–840	Chlorpropamide Tablets USP, 100 mg

Application No.	Drug
ANDA 88–932	Reserpine and Hydroflumethiazide Tablets, 0.125 mg/50 mg

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 January 5, 1998.

Dated: November 17, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–31879 Filed 12–4–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs 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: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on December 18, 1997, 8:30 a.m. to 5:05 p.m., and December 19, 1997, 8 a.m. to 4:35 p.m.

Location: Holiday Inn, Versailles Ballrooms I, II, and III, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Jannette O'Neill-Gonzalez, or Robinette Taylor, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 18, 1997, the committee will discuss: (1) New drug application (NDA) supplement 16–295/S–029, Droxia® (hydroxyurea capsules, USP), for the treatment of sickle cell anemia in adult patients to prevent painful crises and to reduce the need for blood transfusions; and (2) NDA 20–798, Depocyt® (cytarabine lipid-particle injection), for the intrathecal treatment of neoplastic meningitis of patients with solid tumors, lymphoma, or leukemia. On December 19, 1997, the committee will discuss: (1) Biologics licensing application (BLA) supplement 97–0501, Proleukin/Aldesleukin (recombinant human interlukin-2), for the treatment of adult patients with metastatic melanoma; and (2) NDA 20–806, Neomark® (broxuridine for injection), for use as a cell proliferation marker to determine the labeling index in breast cancer.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 10, 1997. Oral presentations from the public will be scheduled between approximately 8:35 a.m. and 9:05 a.m. on December 18, 1997, and between approximately 8:05 a.m. and 8:35 a.m. on December 19, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 10, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the December 18, 1997, Oncologic Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Oncologic Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 26, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–31808 Filed 12–4–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0442]

Memoranda of Understanding Between the Food and Drug Administration and the United States Department of Agriculture

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) have revised three memoranda of understanding (MOU's) with regard to control of aflatoxin in peanuts, in-shell Brazil nuts, and in-shell pistachio nuts. The purpose of the MOU's is to set forth the responsibility for aflatoxin testing of domestic and imported raw peanuts, imported in-shell Brazil nuts, and imported in-shell pistachio nuts.

DATES: The MOU's became effective October 1, 1997.

FOR FURTHER INFORMATION CONTACT: Henry Kim, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–0631.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's signed by FDA and other departments, agencies, and organizations shall be published in the **Federal Register**, the agency is publishing three revised MOU's between FDA and USDA that set forth the responsibility for aflatoxin testing of domestic and imported raw peanuts, imported in-shell Brazil nuts, and imported in-shell pistachio nuts.

Dated: November 24, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

The text of the three MOU's follows: Agreement No.