Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA has revoked the establishment license (U.S. License No. 832–003) and the product license for the manufacture of Source Plasma issued to Worldwide Biologicals, Inc., 508–A Owen Dr., Fayetteville, NC 28304.

By letter dated June 15, 1992, issued pursuant to 21 CFR 601.5(b), FDA notified the firm of FDA's intent to revoke U.S. License No. 832–003 and announced its intent to offer an opportunity for a hearing. In a facsimile dated June 24, 1992, the firm notified FDA of its intent to request a hearing on the proposed license revocation.

In the Federal Register of March 22, 1993 (58 FR 15351), FDA issued a notice of opportunity for a hearing, pursuant to 21 CFR 12.21(b), on the proposal to revoke the establishment license (U.S. License No. 832–003) and product license issued to Worldwide Biologicals, Inc., for the manufacture of Source Plasma. As described in the notice of opportunity for a hearing, the grounds for the proposed license revocation included the following: (1) The results of FDA inspections of the firm conducted from June 24 through July 2, 1991; January 17 through January 27, 1992; and May 5 and 6, 1992; as well as from the inspection of Worldwide Biologicals, Inc., 1085 Ohio Pike, Cincinnati, OH, the site of the testing laboratory approved to perform all required testing for the Fayetteville facility, from July 18 through August 26, 1991; (2) a determination by FDA that the deviations documented during the inspections of the firm demonstrated significant noncompliance with the applicable regulations and standards in the firm's license; and (3) a determination by FDA that there was no assurance that the firm would properly implement a corrective action plan that it had proposed. FDA's determination was based on the firm's failure to adequately implement previously promised corrections. Documentation in support of the proposed revocation had been placed on file for public examination with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

Following publication of the notice of opportunity for a hearing on March 22, 1993, FDA's Dockets Management Branch received two letters, dated April 12, 1993, and May 20, 1993, from the firm's responsible head. In the letter of April 12, 1993, Worldwide Biologicals, Inc., requested a hearing on the proposed license revocation. In the letter of May 20, 1993, Worldwide Biologicals, Inc., submitted its request for a hearing and set forth information and factual analyses to support its request.

While the request for a hearing was pending, representatives of the U.S. Department of Justice, on behalf of FDA, charged the responsible head of Worldwide Biologicals, Inc., with criminal violations of Federal laws governing the manufacturing, labeling, and shipping of human blood plasma. On April 6, 1994, the responsible head entered into a plea agreement with the United States Attorney for the Southern District of Ohio and the Office of Consumer Litigation, United States Department of Justice. In a superseding plea agreement filed on April 29, 1994, with the clerk of the United States District Court, Southern District of Ohio, Western Division, the responsible head of the firm agreed to surrender U.S. License No. 832 immediately upon sentencing. Sentencing took place on September 23, 1994. FDA notified Worldwide Biologicals, Inc., by letter of September 29, 1994, that the licenses had been revoked.

Based on the voluntary surrender of U.S. License No. 832, Worldwide Biologicals Inc.'s request for a hearing on the issue of license revocation became moot. Although the revocation proceedings that FDA initiated only pertained to the firm's Fayetteville, NC location (U.S. License No. 832–003), the surrender of U.S. License No. 832 affects all Worldwide Biologicals, Inc., locations under that license.

Accordingly, under 21 CFR 601.5, section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 832–003) and the product license for the manufacture of Source Plasma issued to Worldwide Biologicals, Inc., were revoked, effective September 29, 1994.

This notice is issued and published under 21 CFR 601.8 and the redelegation at 21 CFR 5.67.

Dated: May 2, 1996.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 96–12688 Filed 5–20–96; 8:45 am]

BILLING CODE 4160–01–F

Grassroots Regulatory Partnership Meeting; Pacific Region San Francisco District Office; Medicated Feed Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public meeting.

SUMMARY: The Food and Drug Administration (FDA) (Office of External Affairs, Office of Regulatory Affairs, Office of the Pacific Region, and the Center for Veterinary Medicine) is announcing a free public meeting as a followup to a meeting held in April 1995. FDA's San Francisco District Office (Pacific Region) and the Center for Veterinary Medicine will meet with interested persons in the Pacific Region to address specific issues related to the medicated feed industry to help the industry comply with FDA regulations. The agency is holding this meeting to promote the President's initiative for a partnership approach with front-line regulators and the people affected by the work of this agency.

DATES: The public meeting will be held on Friday, May 31, 1996, from 8 a.m. to 4:30 p.m.

ADDRESSES: The public meeting will be held at the Red Lion Inn, 1401 Arden Way, Sacramento, CA 95815. Attendees requiring overnight accommodations may contact the hotel at 916–922–8041.

FOR FURTHER INFORMATION CONTACT:

Regarding the Sacramento area: Karen L. Robles or Susan R. Nelson, Food and Drug Administration, 650 Capitol Mall, rm. 6002, Sacramento, CA 95814, 916–498–6403 or 916–498–6400 or FAX 916–498–6401.

Regarding the Fresno area: Robert J. Anderson, Food and Drug Administration, 2202 Monterey St., suite 104E, Fresno, CA 93721, 209–487–5321 or FAX 209–487–5305.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 20, 1995 (60 FR 19753), FDA announced that a series of Grassroots Regulatory Partnerships meetings would be held. This document announces a free public meeting as a followup to the meetings held in April 1995. Those persons interested in attending this public meeting should FAX their comments and registration including name, firm/organization, address, telephone and FAX numbers to the appropriate contact person listed above, by Friday, May 24, 1996.

There is no registration fee for this meeting, but advance registration is required. Space is limited and all interested parties are encouraged to register early. The goals of this meeting are to listen to concerns and ideas, and to identify next steps for the agency.

Dated: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12650 Filed 5–20–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95P–0285]

Determination That Glyburide Tablets 4.5 Milligrams Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that glyburide (Glynase® PresTab®) tablets 4.5 milligrams (mg) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow sponsors to submit abbreviated new drug applications (ANDA's) for glyburide tablets 4.5 mg.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the listed drug, which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Another FDA regulation also provides that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Novopharm Ltd., submitted a citizen petition, dated August 21, 1995 (Docket No. 95P–0285/CP1), under 21 CFR 10.25(a) and 10.30 requesting that the agency determine whether glyburide tablets 4.5 mg was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, to keep the drug in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' Glyburide tablets 4.5 mg, along with the 1.5-mg, 3-mg, and 6-mg strengths, is the subject of approved NDA 20–051 held by the Upjohn Co. (Upjohn). Upjohn obtained approval to market the 4.5-mg strength of glyburide tablets on September 24, 1993. Upjohn has never marketed the 4.5-mg strength of glyburide tablets. FDA has determined, for purposes of §§ 314.161 and 314.162(c), that never marketing an approved drug product is equivalent to withdrawing the drug for sale.

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that glyburide tablets 4.5 mg was not withdrawn from sale for reasons of safety or effectiveness and will continue to list glyburide tablets 4.5 mg in the ''Discontinued Drug Product List'' contained in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' The ''Discontinued Drug Product List'' lists, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to glyburide tablets 4.5 mg may be submitted to the agency.

The agency notes that there is a patent listed in the Orange Book for Glynase® PresTab® tablets that will not expire until April 10, 2007. This patent will prevent FDA from approving ANDA's that refer to Glynase® PresTab® tablets with an effective date before April 10, 2007, if the patent is valid and the manufacture, use, or sale of the drug product for which approval is being sought would infringe the patent. Novopharm Ltd., states in its petition that it does not intend to make a generic drug that refers to Glynase® PresTab® tablets available for sale until the expiration of the patent. Between now and the time an ANDA for glyburide tablets 4.5 mg is submitted, approved, or the approval goes into effect, FDA may obtain new information on the safety and effectiveness of glyburide tablets that will prevent the agency from receiving or approving the ANDA.

Dated: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12759 Filed 5–20–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95P–0128]

Determination That Hydrocortisone Acetate Topical Ointment 2.5% Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that hydrocortisone (Cortef®) acetate topical ointment 2.5% was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow sponsors to submit abbreviated new drug applications (ANDA's) for hydrocortisone acetate topical ointment 2.5%.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the listed drug, which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the