DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 19, 2002

Marilyn A. Friedly
PharmaForce, Inc.
1507 Chambers Road
Columbus, Ohio 43212

Re: Docket No. 02P-0127/CP1

Dear Ms. Friedly:

This letter responds to your citizen petition dated March 25, 2002, requesting that the Food and Drug Administration (FDA) determine whether PHENERGAN (promethazine hydrochloride (HCl) injection USP) 25 milligrams (mg)/milliliter (mL), 10 mL (NDA No. 08-857), previously marketed by Wyeth Laboratories Inc., was voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

The FDA has reviewed its records and determined that PHENERGAN (NDA No. 08-857) was not withdrawn from sale for reasons of safety or effectiveness. The FDA will maintain PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, in the "Discontinued Drug Product List" of *Approved Drugs with Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 594-5638.

Sincerely,

Nikki Mueller
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

02P-0127 LET 2

Committee Name	Dates of Meetings	Advisory Committee 5-Digit Information Line Code
Hematology and Pathology Devices Panel	March 14, June 20, October 3	12515
Immunology Devices Panel	March 17–18, June 9–10, September 15–16	12516
Medical Devices Dispute Resolution Panel	No meetings planned	10232
Microbiology Devices Panel	March 27–28, May 5–6, August 7–8, October 16–17	12517
Molecular and Clinical Genetics Panel	April 24–25, July 17–18, November 13–14	10231
Neurological Devices Panel	March 6–7, June 23–24, September 18–19, December 8–9	12513
Obstetrics and Gynecology Devices Panel	March 3–4, June 9–10, September 8–9, November 3–4	12524
Ophthalmic Devices Panel	March 13–14, May 22–23, July 10–11, September 11–12, November 6–7	12396
Orthopaedic and Rehabilitation Devices Panel	February 20–21, May 29–30, August 27–28, November 20–21	12521
Radiological Devices Panel	February 4, May 20, August 12, November 18	12526
National Mammography Quality Assurance Advisory Committee	April 7–8, September 8–9	12397
Technical Electronic Product Radiation Safety Standards Committee	June 18	12399
CENTER FOR VETERINARY MEDICINE		
Veterinary Medicine Advisory Committee	May 15, September 15	12548
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants	February 10–13, June 23–25	12560
Science Advisory Board to the National Center for Toxicological Research	June 3–5	12559

Dated: December 12, 2002.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 02–31994 Filed 12–18–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P–0127]

Determination That PHENERGAN (Promethazine Hydrochloride Injection USP) 25 Milligrams/Milliliter, 10 Milliliters, 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 PHENERGAN (promethazine hydrochloride (HCl) injection USP) 25 milligrams (mg)/milliliter (mL), 10 mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for promethazine HCl injection USP 25 mg/mL, 10 mL.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 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 ANDAs 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 include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), 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 (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine 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. FDA may not approve an ANDA that does not refer to a listed drug.

PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, is the subject of approved NDA 08–857 held by Wyeth Pharmaceuticals, a division of Wyeth. PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, is indicated for certain types of allergic reactions and sedation. In a citizen petition dated March 25, 2002 (Docket No. 02P–0127), submitted under § 314.161 and 21 CFR 10.30, PharmaForce, Inc., requested that the agency determine whether PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, was withdrawn from sale for reasons of safety or effectiveness. The petitioner seeks this determination in preparation for filing an ANDA for promethazine HCl injection USP 25 mg/mL, 10 mL.

The agency has determined that Wyeth's PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, was not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, we note that Wyeth continues to market PHENERGAN for injection in 25 mg/mL and 50 mg/mL, 1-mL vials. The 25 mg/mL, 10 mL product is a multidose vial consisting of the same drug as the 25 mg/mL and 50 mg/mL, 1-mL vials. Also, promethazine HCl is a widely used product that has been marketed for many decades in many dosage forms. Although one potential concern with any multidose injectable product is the possibility of accidental overdose, there is no evidence that the withdrawal from the market of PHENERGAN (promethazine HCl injection) 25 mg/mL, 10 mL, was in any way connected to accidental overdose. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, Wyeth's PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, may be approved by the agency.

Dated. December 8, 2002

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc 02–31910 Filed 12–18–02; 8.45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0289]

Medical Devices; Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." This guidance will serve as a special control for the absorbable polydioxanone surgical (PDS) suture which is being reclassified from class III to class II (special controls) elsewhere in this issue of the **Federal Register**. This guidance document is immediately in effect as the special control for the absorbable PDS suture, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

Also, elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend eight other surgical suture device classification regulations in order to designate this guidance as the special control for each such device. After public comments are reviewed, FDA intends to issue a final rule for the eight other surgical sutures and make this guidance effective as the special control guidance for those sutures in addition to the PDS suture, for a total of nine suture types. This guidance is not final nor is it in effect at this time for the eight surgical sutures for which it is being proposed as a special control.

DATES: Submit written or electronic comments concerning this guidance by March 19, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.