

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2005P-0300 and 2005P-0319]

**Determination That PHENERGAN (Promethazine Hydrochloride) Tablets,
12.5 Milligrams and 50 Milligrams, Were Not Withdrawn From Sale for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has determined that PHENERGAN (promethazine hydrochloride (HCl)) tablets, 12.5 milligrams (mg) and 50 mg, were not withdrawn from sale for reasons of safety or effectiveness.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 tablets, 12.5 mg and 50 mg.

FOR FURTHER INFORMATION CONTACT: Quynh Nguyen, 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 (the 1984 amendments) (Public Law 98-417), 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. Sponsors of ANDAs do not have to repeat the extensive clinical

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testing otherwise necessary to gain approval of a new drug application (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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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) tablets, 12.5 mg and 50 mg, are the subject of approved NDA 7-935 held by Wyeth Pharmaceuticals, Inc. (Wyeth). PHENERGAN (promethazine HCl) tablets are indicated for, among other things, certain types of allergic reactions and sedation. Wyeth's NDA 7-935 was originally approved in 1951. In 1971, under the Drug Efficacy Study Implementation (DESI), FDA concluded that promethazine HCl tablets were effective or probably effective for the indications described in the **Federal Register** notice published on June 18, 1971 (DESI 6290, 36 FR 11758). Wyeth discontinued sale of the 12.5 mg and 50 mg tablets in 2004. Amide Pharmaceutical, Inc., and Peter S. Reichertz submitted citizen petitions dated

July 28, 2005 (Docket No. 2005P-0300/CP1), and August 10, 2005 (Docket No. 2005P-0319/CP1), respectively, under 21 CFR 10.30, requesting that the agency determine, as described in § 314.161, whether PHENERGAN (promethazine HCl) tablets, 12.5 mg and 50 mg, were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Wyeth's PHENERGAN (promethazine HCl) tablets, 12.5 mg and 50 mg, were not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, we note that promethazine HCl is a widely used product that has been marketed for many decades in many dosage forms. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate that PHENERGAN tablets, 12.5 mg and 50 mg, were withdrawn for reasons of safety or effectiveness.

After considering the citizen petitions (including comments submitted) and reviewing agency records, FDA determines that for the reasons outlined previously, Wyeth's PHENERGAN (promethazine HCl) tablets, 12.5 mg and 50 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list PHENERGAN (promethazine HCl) tablets, 12.5 mg and 50 mg, 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) tablets, 12.5 mg and 50 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs.

Dated: 6/30/06
June 30, 2006.


Jeffrey Shuren,
Assistant Commissioner for Policy.

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