

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P-0104]

2-9-06
2-10-06
L. CLAWSON
DDM

Determination That PEPTAVLON (Pentagastrin) for Subcutaneous Injection, 0.25 Milligrams per Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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determined that PEPTAVLON (pentagastrin) for subcutaneous injection, 0.25 milligrams (mg) per milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness.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 pentagastrin for subcutaneous injection, 0.25 mg/mL.

FOR FURTHER INFORMATION CONTACT: Tawni B. Schwemer, 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 typically a version of the drug that was

previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical 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.

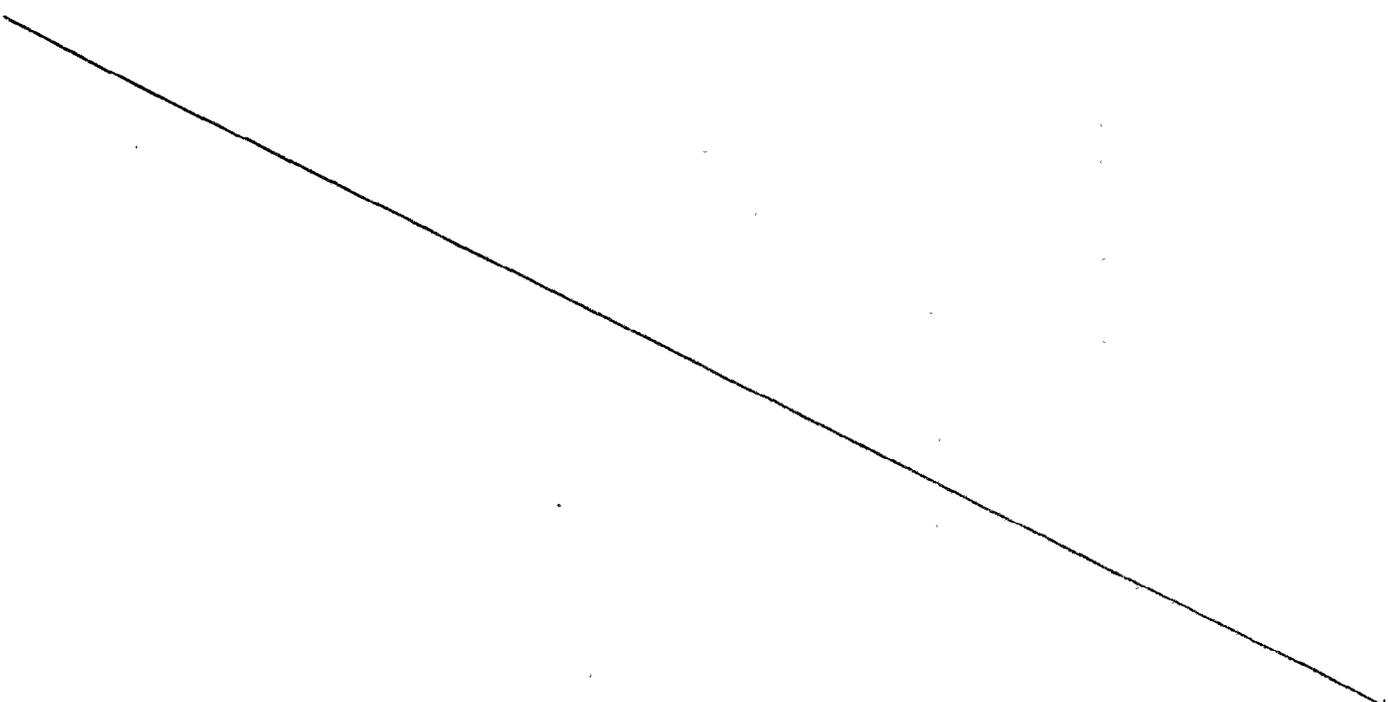
The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally 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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the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).

PEPTAVLON for subcutaneous injection is the subject of approved NDA 17-048 held by Wyeth Ayerst Laboratories (Wyeth Ayerst). PEPTAVLON (pentagastrin) for subcutaneous injection is a testing agent to help diagnose problems or diseases of the stomach. This test determines how much acid a patient's stomach produces.

PEPTAVLON for subcutaneous injection, 0.25 mg/mL, was approved on July 26, 1974. Wyeth Ayerst ceased manufacture of PEPTAVLON for subcutaneous injection, 0.25 mg/mL, in March 2002, and requested that FDA withdraw approval of the NDA (68 FR 49481, August 18, 2003). Therefore, it was moved from the "Prescription Drug Product List" to 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.

Under 21 CFR 314.161(a)(3), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness when a person petitions for such a determination under 21 CFR 10.25(a) and § 10.30 (21 CFR 10.30).

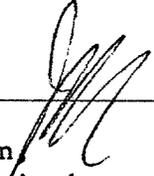
Arnall Golden Gregory LLP submitted a citizen petition dated March 7, 2005 (Docket No. 2005P-0104/CP1), under § 10.30, requesting that the agency determine whether PEPTAVLON (pentagastrin) for subcutaneous injection, 0.25 mg/mL, was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing agency records, FDA has determined that PEPTAVLON for subcutaneous injection, 0.25 mg/mL, approved under NDA 17-048, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that PEPTAVLON (pentagastrin) for subcutaneous injection, 0.25 mg/mL, was withdrawn from sale as a result of safety or effectiveness concerns. FDA's independent evaluation of relevant literature and data has not uncovered anything that would indicate that this product was withdrawn for reasons of safety or effectiveness. Accordingly, the agency will continue to list PEPTAVLON (pentagastrin) for subcutaneous injection, 0.25 mg/mL, in the



“Discontinued Drug Product List” section of the Orange Book. ANDAs that refer to PEPTAVLON for subcutaneous injection, 0.25 mg/mL, may be approved by the agency.

Dated: 2/2/06

February 2, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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