



Food & Drug Administration  
Olympic Towers, Suite 100  
300 Pearl Street  
Buffalo, NY 14202

January 16, 1998

**WARNING LETTER BUF #98-5**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Bernard Poussot, President  
Wyeth-Ayerst Laboratories  
P.O. Box 8299  
Philadelphia, Pennsylvania 19101-8299

Dear Mr. Poussot:

During an inspection of your manufacturing facility November 18, 19, 20, 25 and 26, 1997, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, *CODE OF FEDERAL REGULATIONS*, Parts 210 and 211). The deviations listed below cause your drug product, Mepergan Fortis Capsules, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

1. Failure to adequately validate the manufacturing process [21 CFR 211.110(a)].
2. Failure to properly qualify the [REDACTED] Filler, Asset # [REDACTED] used on packaging line # [REDACTED] [21 CFR 211.68].

These violations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters concerning drugs so they may take this information into account when considering the awarding of contracts. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval, requests may not be approved until the above violations are corrected.

We are in receipt of a letter dated December 23, 1997, from William E. Brooks, Managing Director of your manufacturing facility located in Rouses Point, New York. The letter responds to the List of Observations, form FDA-483, issued at the conclusion of the November inspection of your firm. The response will be made a part of our file for your firm.

Your December 23, 1997, response is inadequate because it states additional lots of Mepergan Fortis Capsules will be manufactured prior to conducting manufacturing process validation. You should be aware, during the inspection our investigator reviewed results of sampling drums of granulation which revealed de-mixing of the granulation after blending and prior to encapsulation. Your response does not indicate the steps to be taken to assure current and future lots of marketed product meet compendial and NDA requirements.

Bernard Poussot, President

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You should take prompt action to correct these deviations. Failure to achieve prompt correction may result in regulatory action, without further notice. This may include seizure and/or injunction.

Please notify this office, in writing, within 15 days of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should address products in commercial distribution and should be directed to William J. Thompson, Team Leader, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "B. J. Holman", followed by a vertical line and a small mark.

Brenda J. Holman  
District Director

amb

cc: William E. Brooks, Managing Director  
Wyeth-Ayerst Laboratories  
64 Maple Street  
Rouses Point, New York 12979