305

DEPARTMENT OF HEAL & HUMAN SERVICES

FEB 10 2006

Food and Drug Administration
Rockville MD 20857

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Alan G. Minsk
David Hoffman
Arnall Golden Gregory LLP
171 17th Street, N.W.
Suite 2100
Atlanta, GA 30363

Re: Docket No. 2005P-0104/CP1

Dear Messrs. Minsk and Hoffman:

This letter responds to your citizen petition dated March 7, 2005, requesting that the Food and Drug Administration (FDA) determine that Wyeth Pharmaceutical's Peptavlon (pentagastrin) injection, 0.25mg/mL (NDA No. 17-048), was withdrawn from sale for reasons of safety or effectiveness and, therefore, a new drug application (NDA) may be submitted and approved under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the Act).

The FDA has reviewed its records and determined that Peptavlon (pentagastrin) injection, 0.25 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Peptavlon (pentagastrin) injection, 0.25 mg/mL, in the *Discontinued Drug Product List* of the *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book). Please note that an FDA determination that this drug was not withdrawn from sale for reasons of safety or effectiveness [under 21 CFR 314.161] was not required for you to submit an NDA under section 505(b)(2).

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 301-594-2041.

Sincerely,

Tawni B. Schwemer

Tawni B. Schwemer
Division of Regulatory Policy II
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

2005P-0104

LET 2