



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP -7 2005

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

Re: Docket No. 2005P-0104/CP1

Dear Mr. Minsk:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on March 15, 2005. Your petition requests that the Agency make a determination that Wyeth Pharmaceuticals' new drug application (NDA) 17-048, Peptavlon (pentagastrin) for Subcutaneous Injection was voluntarily withdrawn from sale for reasons other than safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

CC: David Hoffman
Arnall Golden Gregory LLP

2005P-0104

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