DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 16 2003

Mr. Gary Yingling
Kirkpatrick & Lockhart, LLP
1800 Massachusetts Avenue, N.W.
Washington, D.C. 20036-12211

Re: Docket No. 02P-0483/CP1

Dear Mr. Yingling:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition submitted on November 12, 2002, on behalf of several pharmaceutical manufacturers and distributors. Your petition requests that the Agency reconsider its regulatory approach with respect to single ingredient extended release guaifenesin drug products and, by extension, to other long-marketed yet unapproved drug products.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

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

cc: David L. Durkin
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