



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 21 2005

Food and Drug Administration
Rockville MD 20857

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Mr. J. Everett Milott
Phelon Parts, Inc.
P.O. Box 2804
Santa Isabel, PR 00757-2804

Re: 2005P-0035/CP1

Dear Mr. Milott:

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 January 24, 2005. Your petition requests that the Agency issue an order authorizing Phelon Parts, Inc. to purchase and use nitrous oxide gas in non-pharmaceutical manufacturing.

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

2005P-0035

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