



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

*5167*  
*HFI-35*  
New York District

Food & Drug Administration  
158-15 Liberty Avenue  
Jamaica, NY 11433

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Andre Engel  
President  
Gel Spice Company, Inc.  
48 Hook Road  
Bayonne, NJ 07002

FEB 12 2001

**REF: NYK-2001-43**

Dear Mr. Engel:

The Food and Drug Administration (FDA) has information which shows that your firm violated the Federal Food, Drug and Cosmetic Act.

On December 18, 19, 2000 and January 10, 2001 FDA attempted to collect a sample of Brazilian black pepper. This product was offered for admission into the United States through the Port of New York/New Jersey under entry number DP4-0171509-0. All-Ways Forwarding International Inc., Jersey City, NJ, filed this entry on November 10, 2000. All entries of Brazilian black pepper are subject to FDA's Import Alert 28-04, accordingly this shipment was detained without examination on November 17, 2000. Your agent (Bill Hollywood, Basic Commodities) conducted product sampling. This sample was collected from warehouse number BBP-01075; a 450-bag lot of black pepper stored at your 48 Hook Road, Bayonne, NJ plant. Our attempted audit examination/sample collection found none of the subject lot remains at your facility.

This action taken by your firm is a violation of 21 CFR 1.90, which requires an importer to hold an entry intact pending receipt of a "May proceed" or "Release Notice" from FDA. A "Release" by the U.S. Customs Service is a conditional release, which merely permits you to take possession of the shipment. When other Federal agencies, such as FDA also exercise jurisdiction over a product offered for importation, its release must be obtained before any of the product may be legally distributed.

Failure to promptly correct this violation and prevent future premature distribution of imported product may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs Service, such as in a bonded warehouse. You will be responsible for all costs incurred in secured storage.

In addition, we are requesting U.S. Customs Service to order redelivery of the shipment of black

**Mr. Andre Engel, President**  
**Gel Spice Company, Inc.**

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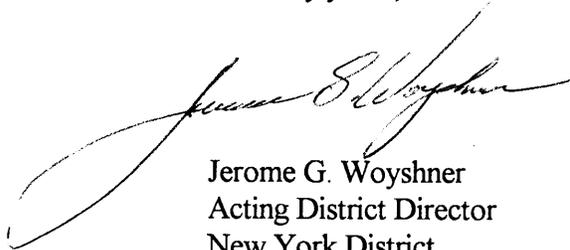
pepper (notice included).

Within fifteen (15) working days of receipt of this letter, please notify our office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step being taken to prevent reoccurrence of the violation.

A copy of this letter, except for confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will also be on public display with any confidential, personal or commercial information purged.

Your response should be addressed to the Food and Drug Administration, Attention: Joseph V. Sollazzo - Compliance Officer, Port Elizabeth Resident Post, 1201 Corbin Street, Elizabeth, New Jersey 07201 (telephone 732-645-2386 extension 20)

Sincerely yours,



Jerome G. Woyshner  
Acting District Director  
New York District

Attachment: Redelivery Request

All-Ways Forwarding International, Inc  
Suite 300  
700 Newark, Avenue  
Newark, NJ 07208