



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

March 18, 2002

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-35

Donald C. Lowery, President  
Lowery Specialty Foods Company  
8326 164<sup>th</sup> Street SE  
Snohomish, Washington 98291

WARNING LETTER

Dear Mr. Lowery:

On October 11 & 15, 2001, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 17381 Tye Street SE, Unit #5, Monroe, Washington. During the inspection, our investigator collected labels for your flavored coffees. Our review of these labels found the above product to be in violation of section 403 of the Federal, Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101-Food Labeling. You can find this Act and the Food Labeling regulations through links in FDA's homepage at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

1. The label for each of your flavored coffees fails to bear a list of ingredients in accordance with section 403(i)(2) of the Act and 21 CFR 101.4. Ingredients shall be listed in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of 21 CFR 101.2.
2. Most of the flavors used in your coffees are derived, in part, from artificial flavors. However, the characterizing flavors designated on the labels of these coffees do not declare that the flavors are artificial in accordance with 21 CFR 101.22(i)(2). For the coffees that contain any artificial flavor that simulates, resembles or reinforces the characterizing (or designated) flavor, the flavor designation on the labels must be accompanied by the words "artificial" or "artificial flavored" in letters not less than on half the height of the lettering used in the declared flavor.

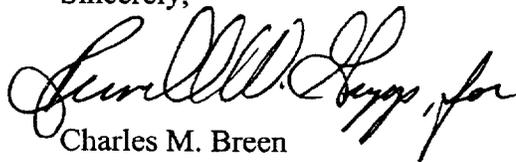
Donald C. Lowery, President  
Lowry Specialty Foods Company, Monroe, WA  
Re: Warning Letter 02-35  
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The above violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa M. Elrand at (425) 483-4913.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen" with a stylized flourish at the end.

Charles M. Breen  
District Director

cc: WSDA with disclosure statement