



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

October 12, 2001

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-02

Michael T. Maher, President  
Fair Scones, Inc.  
15500 Woodinville-Redmond Road, C400  
Woodinville, Washington 98072

**WARNING LETTER**

Dear Mr. Maher:

On August 29, 2001, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 15500 Woodinville-Redmond Road, Woodinville, Washington. During the inspection, our investigator collected Documentary Sample 142363, Fisher The Original Famous Fair Scone, for label review. Our analysis of this label finds the products contained within this packaging to have serious deviations from Title 21 of the Code of Federal Regulations 21 CFR Part 101- Food Labeling and to be in violation of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act). 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 product label collected as Documentary Sample 142363 is misbranded within the meaning of Section 403(q)(1) of the Act in that its labeling fails to include mandatory nutrition facts information. In accordance with 21 CFR 101.9, these products are misbranded in that they fail to list the nutritional information as described within that regulation. And as of July 24, 2001, in accordance with 21 CFR 101.9 (j)(1), a small business labeling exemption has not been filed by your firm. I have included forms and instructions with this correspondence which will assist you with this process.
2. The product label collected as Documentary Sample 142363 is misbranded within the meaning of Section 403(i)(2) of the Act in that its labeling fails to list the common or usual name of each ingredient contained within the product. In accordance with 21 CFR 101.4(a)(1), all ingredients are required to be declared on the label or labeling of food and shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or information panel for that product. The principal display

Michael T. Maher, President.  
Fair Scones, Inc., Woodinville, Washington  
Re: Warning Letter 02-02  
Page 2

panel (PDP) is that portion of the package that is most likely to be seen by the consumer at the time of purchase. The information panel is the label panel immediately to the right of the PDP, as displayed to the consumer. Our investigator collected documentation showing that this product also contains wheat flour. This ingredient has been identified as a known food allergen, which can cause allergic reactions in a small percentage of the population.

3. The product label collected as Documentary Sample 142363 is misbranded within the meaning of Section 403(e)(2) of the Act in that its labeling does not contain an accurate statement of the quantity of the contents in terms of weight. In accordance with 21 CFR 101.105(a), the net quantity of contents is the statement on the label, which provides the amount of food in the container or package. This statement is placed on the principal display panel of the product and is listed in both metric and U.S. Customary system.

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. 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.

For your information, our investigator noted that your firm believes that the airline's use of your products exempts you from the labeling violations addressed in this letter. Products that are prepackaged and intended to be opened by airline passengers require legal labeling and are subject to all the laws and regulations discussed in this letter. In addition, your labeling of the fair scone products also requires a street address in accordance with 21 CFR 101.5(d), since your firm was not listed in the current Medina City directory.

Our investigator stated in his report concerning the recent inspection of your firm, that your firm no longer manufactures [REDACTED]. During a previous inspection on August 21 and 24, 2000, samples of this product were collected by our investigator for laboratory analyses. These samples were identified as 104835, 104836, and 104837. Our Pacific Regional Laboratory Northwest analyzed these samples for pH and water activity. The pH and water activity levels found in your crumpets, and the fact that a vacuum is pulled on the pouches and the contents flushed with carbon dioxide, may be conducive to the growth of *Clostridium botulinum*. *Clostridium botulinum* is a sporeforming bacterium which, under the right conditions, can grow in the absence of oxygen. When it is allowed to grow, it produces a deadly toxin. Since your crumpets were not refrigerated or frozen after production or while in distribution channels, the conditions could have been favorable for the growth of this pathogen. In addition, since this product was hand-filled, and received no further heat treatment or kill step after packaging, the products were also susceptible to the introduction of *Staphylococcus aureus*. This pathogen can also grow in the absence of oxygen and produce an enterotoxin that can cause illness or death. The FDA is pleased that you have discontinued this product, and we have now provided our concerns to you, should you decide to reintroduce this product as part of your product line.

Michael T. Maher, President  
Fair Scones, Inc., Woodinville, Washington  
Re: Warning Letter 02-02  
Page 3

Please respond in writing within 15 working days 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: Diane J. Englund, 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 Diane J. Englund at (425) 483-4864.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen  
District Director

Enclosures:

Section 403 of the Federal Food, Drug, and Cosmetic Act  
21 CFR Parts 101.4, 101.5, 101.9, and 101.105  
Small Business Food Labeling Exemption Forms

cc: WSDA with disclosure statement