



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

September 11, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-84

Stephen Wurster, President/Owner
Buns Master Bakery, Inc.
7304 Lakewood Drive West
Lakewood, Washington 98499

WARNING LETTER

Dear Mr. Wurster:

On January 4, 2001, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 7304 Lakewood Drive West, Lakewood, Washington. During the inspection, our investigator collected labels for four products, kaiser buns, french dip rolls, pizza shells (7 inch) and pizza shells (12 inch). Our review reveals this label causes 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.

The deviations are as follows:

1. The label for french dip rolls fails to bear a list of ingredients in order to comply with 21 CFR 101.4(a)(1). 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. The labels for kaiser buns, 7 inch pizza shells, and 12 inch pizza shells do not list sub-ingredients of enriched flour, soya flour, and shortening in order to comply with 21 CFR 101.4(b)(2). One way to comply is to declare the common name of the ingredient followed by a parenthetical listing of its ingredients in descending order of predominance.
3. The label for french dip rolls fails to bear nutritional labeling to comply with 21 CFR 101.9. Nutritional information relating to food shall be provided for all products intended for human consumption. This product is not exempt under 21 CFR 101.9(j)

Stephen Wurster, President/Owner
Buns Master Bakery, Inc., Lakewood, Washington
Re: Warning Letter 01-84
Page 2

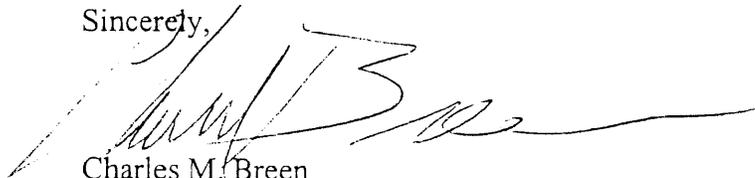
4. The label for french dip rolls fails to bear an appropriate statement of identity and common or usual name. The label has a sticker on the back of the package that has a bar code and the words "FRENCH DIP". The statement of identity must appear on the principal display panel to comply with 21 CFR 101.3(a), and must be in terms of a common or usual name or in the absence of a common or usual name an appropriately descriptive term to comply with 21 CFR 101.3(b).
5. The label for french dip rolls fails to bear a declaration of the net quantity of contents to comply with 21 CFR 101.105.

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 23rd 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", written over a horizontal line.

Charles M. Breen
District Director

cc: WSDA with disclosure statement