



DEPARTMENT OF HEALTH AND HUMAN SERVICES

g3724d
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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November 26, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 03-05

George W. Miller, Co-Owner
Puget Sound Baking Company, LLC
18005 Northeast 68th Street, Suite A-150
Redmond, Washington 98052

WARNING LETTER

Dear Mr. Miller:

The Food and Drug Administration (FDA) conducted an inspection of your bakery located at 18005 Northeast 68th Street, Suite A-150, Redmond, Washington, on October 23, 24, 25, 28, 29, 30, and 31, 2002. The inspection revealed numerous deviations from the Current Good Manufacturing Practice (CGMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110. At the conclusion of the inspection, you were issued a Form FDA-483 (copy enclosed), Inspectional Observations, which delineated a number of gross insanitary conditions present in your bakery at the time of the inspection. These conditions cause the bakery products manufactured in your facility to be adulterated within the meaning of Sections 402(a)(3) and 402(a)(4) (copy enclosed) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(3) and 21 U.S.C. § 342(a)(4). You can find this Act through links in FDA's homepage at www.fda.gov.

The raw materials for your bakery products are adulterated under Section 402(a)(3) of the Act in that they consist in whole or in part of filthy substances, i.e., beetles. In addition, the insanitary conditions at your facility cause your bakery products to be adulterated under Section 402(a)(4) of the Act because they have been prepared, packed, or held under conditions whereby they may have become contaminated with filth from beetles, flies, and bird excreta droppings.

The following is a list of the insanitary conditions observed by our investigators during the inspection:

BEETLE ACTIVITY:

1. Live beetles were observed both on the surface of, and within, the following raw materials:

- a) approximately 50 live beetles were observed on the surface of, and additional beetles observed within, bags of [REDACTED] All Purpose Flour;
 - b) at least 10 live beetles were observed on the surface of bags of [REDACTED] Buttermilk Bread Base, and four live beetles were observed within one bag; and
 - c) at least four live beetles were observed on the surface of, and one within, bags of [REDACTED] Devils Food Mix.
2. Live and dead beetles were observed on the surfaces, or within the plastic linings, of the following raw materials:
- a) at least 12 dead beetles on the surface of a bag of [REDACTED] Quick Rolled Oats;
 - b) approximately 25 dead beetles within the plastic lining of a bag of [REDACTED] chocolate; and
 - c) approximately 25 dead beetles within the plastic lining of a bag of [REDACTED] stabilizer stored on a shelf adjacent to the west wall.
3. Live and dead beetles were observed in the following areas of the bakery:
- a) approximately 20 live and dead beetles on the wooden shelves adjacent to the west wall;
 - b) at least 10 beetles observed on the top outside rim, and at least six dead beetles observed in the electrical box, of a [REDACTED] bread mixer used to make bread and glazed donuts during the inspection;
 - c) at least twenty-five live beetles in a damp cloth used to stabilize the leg of a prep table and at least five beetles observed on the surface and sides of this table;
 - d) two live and one dead beetle on a metal scaling table on the north wall that is used to store raw materials;
 - e) at least five live beetles on the surface of a wooden scaling table;
 - f) five live beetles at the floor/wall juncture between two [REDACTED] ovens; and
 - g) three dead beetles on a metal storage bin containing Devil's Food Cake Mix, east of the [REDACTED] mixers.

BIRD ACTIVITY:

4. Bird activity and evidence were observed in the following areas of the bakery:
- a) three live birds were observed flying throughout the processing area directly over cooked, ready-to-eat products, and raw materials;
 - b) bird excreta droppings were observed on bags of [REDACTED] Cinnamon Roll Mix, [REDACTED] Buttermilk Bread Base Mix, [REDACTED] All Purpose Flour, [REDACTED] Whole Wheat Flour, [REDACTED] Quick Rolled Oats, [REDACTED] Éclair/Cream Puff Mix, [REDACTED] Muffin Mix, and Corn Muffin Mix; and
 - c) a fan used to cool finished product at a range of approximately 12 inches contained four bird feathers in the fan grill.

George W. Miller, Co-Owner
Puget Sound Baking Company, LLC, Redmond, Washington
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FLY ACTIVITY:

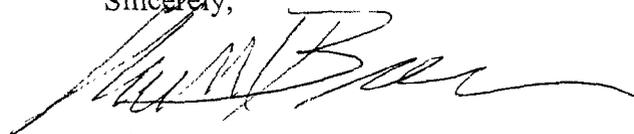
5. Fly activity was observed in the following areas of the bakery:
 - a) two live flies were observed on the edge of a mixing bowl containing product;
 - b) live flies were observed flying throughout the processing area and landing on food contact surfaces;
 - c) two dead flies were observed on a tray containing rising dough;
 - d) and one dead fly was observed on a tray containing cream puffs.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. 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. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar, Compliance Officer, at (425) 483-4940.

Sincerely,



Charles M. Breen
District Director

Enclosures:

Form FDA 483

21 CFR PART 110

Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement