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DEC 21 2005

Mr. George M. Burditt
Bell, Boyd & Lloyd LLC
70 West Madison Street, Suite 3100
Chicago, Illinois 60602-4207

Re: Docket 2005P-0269/CP1

Dear Mr. Burditt:

This letter responds to the citizen petition, dated June 24, 2005, and filed on June 28, 2005, that you submitted on behalf of Claxton Bakery, Collin Street Bakery, Grandma's Bake Shoppe and M. K. Commercial Kitchens, Inc. Your petition requested that FDA amend Title 21 of the Code of Federal Regulations (21 CFR) 101.12(b) Table 2 by establishing a separate reference amount customarily consumed per eating occasion (reference amount) for fruitcake. Specifically, you requested that FDA amend 21 CFR 101.12(b) Table 2 by removing fruitcake from the product category of "Cakes, heavy weight ..." with a reference amount of 125 grams (g), and establishing a separate product category for "Fruitcakes" with a reference amount of 43 g.

In accordance with 21 CFR 10.30(e)(2), this letter is to advise you that FDA is denying your petition without prejudice to the future filing of a petition accompanied by sufficient supporting data.

The information you provided in your petition does not include consumption data to support the requested change. Essentially, you are asking FDA to create a new subcategory of food (e.g., fruitcake) with its own reference amount (43 g). As mandated by Congress, reference amounts, which are the basis for serving sizes on labels, must be based on the amount customarily consumed. Therefore, without supporting data, your petition is inadequate and cannot be reviewed.

Specifically, you have failed to provide FDA with (1) data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the reference amount of the parent category (heavy weight cakes) to warrant a separate reference amount (These data must include the information required in 21 CFR 101.12(h)(11)(i) as well as documentation that supports the differences in dietary usage and product characteristics that affect the consumption size that distinguishes the petitioned product from the rest of the products in the category (see 21 CFR 101.12(h)(11)(ii)); and (2) food consumption data that are in accordance with the guidelines set forth in 21 CFR 101.12 (h)(13).

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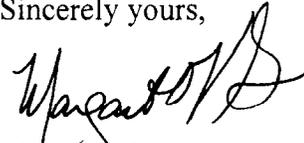
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Because you have failed to adequately support your petition with appropriate food consumption data, we have determined that there are not sufficient grounds to initiate rulemaking to establish a separate product subcategory for fruitcake with a smaller reference amount.

For the reasons stated above, FDA is denying your petition.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Margaret O'K. Glavin". The signature is written in a cursive style with a large, prominent initial "M".

Margaret O'K. Glavin
Associate Commissioner
for Regulatory Affairs