

asi/90667 2703 °03 DEC 23 All:17

December 19, 2003

Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane, rm. 1061 Rockville, MD 20852

Re: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sirs,

Our company has been for many years a supplier of edible products to U.S. firms for corporate promotions. We are represented in the U.S. by a network of independent sales representatives, and our customer list includes several hundred U.S. promotional product distributors. We are operating in compliance with the Bio-Terrorism Act and all other laws and regulations governing cross-border trade, and we are deeply concerned for many reasons about the impact on our business of the new provisions relating to prior notice.

- 1. Taylor & Grant has, since its inception, been proactive in ensuring that its products are labeled with proper ingredient and nutritional information. It is an ongoing source of frustration for our company that our goods, because they cross an international border to enter the United States, are subject to a level of scrutiny which is not applied to competitive product which is manufactured in the U.S. Labeling compliance represents an average cost disadvantage of approximately 3%. Our lobbying efforts with the FDA to create a "level playing field" with regard to this issue have, to date, been unsuccessful, as many of our U.S. competitors continue to sell product which is not labeled. The requirements which prior notice regulations impose on our company further disadvantage our position compared to U.S. manufacturers.
- 2. Our industry operates in a custom, rapid turnaround environment. Average lead time for orders is less than two weeks. Many require turnarounds of less than five days to meet fixed event dates, and samples for client presentations are expected overnight. Each promotional item which we sell is imprinted or otherwise customized with a corporate logo and/or specific message. Thus, it cannot be supplied from a stocked inventory on either side of the border.

2002 N -0276

Each day we ship to a large number of U.S. customers orders which vary in size from less than one hundred dollars to several thousand dollars. Eighty-five percent of our orders have a value of less than \$1,000. Brokers are now applying preparation and filing charges which are based on the number of consignees on a shipment manifest, and the number of FDA-coded products destined for those consignees. Many of our edible products are combinations of items which involve multiple FDA codes. Thus, with our product mix, the compounding effect of these classifications generates a cost for prior notice which is enormous in relation to the value of a typical shipment. On small orders, ones with many items, or drop shipments to multiple consignees, filing costs can be large enough to create a loss.

3. The new regulations exacerbate our concerns about remaining competitive in a time-sensitive industry. We are already experiencing significant delays on shipments which cross the border on Fridays due to the FDA's limited hours on that day. With the new prior notice conditions we feel increased uncertainty regarding transit times and serious concerns that customers' date-sensitive orders will not be received on time. Due to the number and varied nature of our shipments as described above, in addition to the minimum two hours prior notice required by FDA, our customs brokers need up to an additional twelve hours to process manifest information for submission to FDA. This means that, in essence, we have to prepare and manifest shipments one day earlier than previously necessary. We cannot declare quantities in advance because our imprinting and other customization processes involve some scrap. In an industry which expects turnarounds of five days or less, we are seriously disadvantaged. Next-day response to sample requests, which is also an expectation among our customers, has been eliminated.

We respect the intent of the Bio-Terrorism Act to protect individuals residing in the United States. However, we feel strongly that the prior notice provisions are punitive to foreign suppliers such as our company, and are fundamentally contrary to NAFTA and the spirit of trade relations between the United States and Canada. We ask that you consider the particular requirements of the promotional products industry as noted above, and modify the prior notice conditions which have, in sudden and dramatic fashion, created new and very tangible barriers for exporting firms which provide legitimate benefits to U.S. consumers with well-valued, fully compliant products.

Your truly,

TAYLOR & GRANT SPECIALTIES LIMITED

Dundee Staunton, General Manager.