

From: Jerry Bigam [jerry@kinnikinnick.com]  
Sent: Tuesday, May 11, 2004 12:30 PM  
To: fdadockets@oc.fda.gov  
Subject: BTA Prior Notice Comments

Dear Sir/Madam

Our company is one of the largest suppliers of specialty foods in the US market. We provide gluten free and gluten free/casein free foods for people with differing health conditions (Celiac Disease, ADDH, wheat intolerance, lactose intolerance). One of our most important supply methods is direct to the consumer. We supply overnight delivery (by UPS and DHL) to these customers, many of whom have a difficult time accessing these specialty foods in their local area. Many of our customers indicate they have never been able to obtain the type of food we provide and certainly not at the price we can offer.

Over the past 13 months we have been working with the FDA to try to figure out a way in which our supply program can mesh with the requirements of the BTA. The nature of our business is smaller orders (say 1000 per week) with an average of 10 items per order. This requires up to 10,000 Prior Notices every week. In order for us to handle this type of volume we have had to turn to an electronic interface with your website. The normal manual interface would take on average 3 people working 3 days for each days shipment to input all this data to your website. This would not be possible to manage and I suspect would also cause significant problems on your website. Our response has been to try to develop an electronic interface with the FDA website to process all of this data. Working with your staff, we have managed to come up with an program that we have been able to test on your website and it appears that we can develop all of the PN's we require on a weekly basis with about 30 hours of connected time per week.

We were going to turn on the program this week to see how your website would manage the flow but over the weekend there was another change in your site (Version 1.2) and we are not certain how this may impact the interface. Each time a change occurs we face the possibility of having to revise our program and the very real risk that we may not be able to ship until the computer program is re jugged.

Since Monday when we learned of this new change, we contacted the air courier companies and they cannot tell us what is the impact of this change. Assuming that we can get the pdf info from the FDA website with no delays it would be possible for us to print up the 1000 pages of web Summary Confirmations for each week's shipments. But a major problem would be that in order to provide overnight delivery, all data is currently sent by electronic means to UPS (and DHL) and they can then provide informal clearances as the products are on their way to the port of entry (Louisville and Cincinnati). If hard copy is required, this would mean that the copy would arrive with the product; clearance would have to wait till morning and the shipments would be delayed for an extra day. Considering that we are shipping bakery products with no preservatives, that could significantly affect this delivery system. The other option could be to electronically send the web Summary to UPS and DHL and have it available for FDA purposes. It would mean no hard copy available with each order as a general rule but if there was a requirement the hard copy would exist in the electronic file at the port of import. For Informal clearances would this be acceptable?

As of this moment we have no information from the courier companies as to whether it will be possible to comply with this new change by the May 13 deadline. No one can tell us the impact on their computer systems and whether there is any way to incorporate the web Summary into their method of operation, at least before the May 13 deadline.

I know that the Air Courier companies are working with the FDA on personal delivery items. I would like to emphasize in the strongest terms possible that this type of food supply system provides for one of the safest methods possible. We ship products from the manufacturer (Kinnikinnick) through a secure air courier channel to our customer. At every step of the way "track and trace" is in place. If a food security issue was ever identified we would be in a position to contact every one of our customers that might be impacted within a matter of minutes (by phone and/or email). No other food supply chain offers that possibility. As a rule only general recall measures can be undertaken- not specific customer contact. In addition, the size of the orders and the number of people effected are limited. Unfortunately, the impact of the BTA falls most heavily on companies with the least risk and the smallest food safety exposure. It would not surprise me to find that major food exporters (like Kraft, General Mills) will require fewer Prior Notices in a year that we will require in a week.

We are attempting to comply with all of the FDA requirements under the BTA but find that the regulations have a much larger proportional impact on this type of trade than the

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conventional distribution channels. It is an interesting comment to make that the most secure food supply system is having the most difficult time complying with the food security objectives.

I should note that we also send truck shipments into the USA and the BTA measures that have been implemented for these shipments do not raise a difficulty in meeting the compliance requirements. It is the small individual shipments that are in danger of having to be discontinued.

I would be pleased to provide any other information you may require.

Yours truly

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