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From: Ertter-Prego, Jeannie  
Sent: Tuesday, May 11, 2004 9:44 AM  
To: Dockets, FDA  
Subject: FW: Comment submitted via CFSAN QA-ASK

-----Original Message-----

From: Haizhen Zhang [mailto:sales@twohillstea.com]  
Sent: Friday, May 07, 2004 11:30 AM  
To: Ertter-Prego, Jeannie  
Subject: Comment submitted via CFSAN QA-ASK

Personal Information

Name: Haizhen Zhang  
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Comment:

Tea Two Hills  
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www.twohillstea.com

March 9, 2004

Dear FDA,

We would like to comment on  
your Prior Notice System.

We understand the objectives of the Bioterrorism Act  
of 2002, but we are becoming increasingly disturbed by how the FDA Prior Notice process is  
evolving. We find that this system is very difficult to use and very confusing. There must  
be a way to make this system more efficient and user-friendly so that we can continue to do  
trade with your country.

Our

company is based in British Columbia. We are a small tea-import business and much of our  
livelihood comes from our sales to the United States. We have a large and loyal group of  
customers/stores who really appreciate our fine teas. Each day 5-20 stores order tea and  
herbs from us and the bulk of our sales are  
to the United States. Each store order may include from 5 to 30 different teas  
or/and herbs in various quantities from one pound to more than 20 pounds.

Our

company is small, and the implications of the Prior Notice System and the time and  
complications of filling out the forms is arduous. The Prior Notice system threatens the very  
livelihood of our company. We are gravely concerned and hope that the system will be more  
finely-tuned and made more user friendly so that we can continue to do business with the  
United States.

To explain how

difficult the Prior Notice system has become for our company we will give some examples of  
why it doesn't work. For instance, on the Prior Notice website the product list of green  
teas are separated into many different categories (which is confusing in itself as there  
are several hundred different kinds of green teas which all originate from the same species  
of plant, Camellia sinensis). Yet only one category of tea can be selected each time for  
Prior Notice. Since we carry over 50 different kinds of teas and herbs, it is an unreasonable  
expectation that we must fill out a form for each individual product and each individual  
store. If we have to fill out an 18 page form (which is how the system is set up now!) for  
each tea and each store/customer then we may be spending 6 - 10 hours per day filling out  
Prior Notice forms. For example, if we get 20 orders from different stores, and each store  
orders only 5 different kinds of tea and herbs, and we can only select one name on your list

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for each Prior Notice, we will have to file 100 prior notices !! We cannot afford to hire an individual to only do this job so we are taking time away from our regular jobs of marketing, sales, packing and shipping to do the Prior Notice. What this means is that our shipments will take longer to process, we will be shipping later, and we could potentially lose customers in the process. I am sure that is not the intent of these forms, but in fact that is the result.

We have some suggestions on how to improve the Prior Notice forms so that we can continue to export to your country.

1. Could you please have special conditions for small, pre-approved, low risk companies like ours who carry a very defined group of products? Then we could get a fast pre-approval and save all of us (FDA, Customs, our company and staff, our customers) a lot of time, energy and money. Small companies like ours could be preapproved by a set of standards set by the Canadian and American agencies that oversee the Bioterrorism Act of 2002 and Government Import/Export agencies of our two countries.

2. Your website could catalogue all our basic information. Then it would only need a password to bring up everything like our name, address, product origin etc each time. This information could be held on your website for easy access. Then we could just give you our password each time. You would store all the pertinent information that does not change from one day to the next .like our address, our product information, etc.

3. It would be more efficient if we could select as many types of tea as we need on the list at one time and select different locations for different mail at one time instead many dozens of times we are sure that your website has the capacity to hold all this information.

4. There needs to be a more efficient way to input the customer information. Hand typing each store name and address for every order into the Prior Notice is not a reasonable expectation. Can you hold the information on the website so it could be prompted up as we type the first few letters?

5. We also would like the option of having our shipper/manufacturer/producer information held on the website as well. Again it is very laborious to enter all this information for every single Prior Notice.

We truly believe that changes can be implemented that will work for everyone and will support our connected economies. We need to learn to live and work together. This will only increase the prosperity and cooperation of both countries.

Thanks for your time and consideration in this critical matter. We hope to hear from you soon about how the Prior System is being redesigned to work for us all.

Yours  
very truly,

Haizhen Zhang, CEO  
Two Hills Tea

cc. Mr. Jim Gouk, MLA  
Boundary/Kootenay/Okanagan  
Ms. Renee Umezuki, Sr. Marketing & Trade  
Officer, Int. Agric. & Agri-Food Canada  
The Honourable Ralph Goodale,  
Can. International Trade Tribunal , House of Commons, Ottawa, Ont.