

02N-0278\_emc-000173.txt

comment - docket no. 2002N-0278From: Bresters, T. (International) [t.bresters@tpgpost.nl]  
Sent: Wednesday, May 12, 2004 12:54 PM  
To: fdadockets@oc.fda.gov  
Cc: Jousma, S. (International); DudokvanHeel, M.F. (Pakket-service)  
Subject: comment - docket no. 2002N-0278

Dear Sir, Madam,

For your convenience I send you herewith electronically the comment we have just transmitted by fax to you (with some minor text-corrections).

We would appreciate receiving your confirmation of receipt, and your reaction with regard to our questions.

yours sincerely,

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2002N-0278

EMC173



Royal TPG Post BV

## Fax message

Commercie

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To  
Food and Drug Administration  
Division of docket Management

Fax number  
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From  
Tiddo Bresters  
Number of pages (incl. this page)

Fax number  
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Telephone  
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Date  
12 May 2004

Copy to  
-

### Subject

Docket No. 2002N-0278 (prior notice of imported food)

Dear Sir, Madam,

We took notice of your invitation to comment on all aspects of the prior notice Interim Final Rule, as published in the Federal Register of April 14, 2004.

We already commented the IFR in December 2003 (see EC 342 / Tiddo Bresters). In that comment we called the more principle aspects of the measures to your attention, by laying a link with the universal international mail service obligations we have to provide to the general public, as stated by Dutch postal law and the Acts of the Universal Postal Union (UPU).

By this comment we, once more, would like to draw your attention to the concerns the IFR has caused to our company and its customers, and the questions we are confronted with.

Our current, most imminent questions are the following:

Could you clarify within short notice what the effect is of your publication "New features in the Prior Notice System Interface (PNSI)", Version 1.1. (release date February 29, 2004), in which it is said that mail is split in two Entry Types. Which data exactly have to be provided for which category of mail?

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A second aspect we urgently need to know is whether the date of August 12, 2004 still is valid as the date, from which the prior notice measure will be fully enforced, meaning that from that date onwards any mail items not having been pre-notified and not carrying the pre-notification number provided by FDA will be refused by the competent US authorities. There is unconfirmed information, that the prior notice Final Rule now will be issued in March 2005. Is this correct, and what does this mean for how food items will be dealt with in the period after 12 August 2004?

The concerns we referred to earlier are based on the experience we and our customers have gained with the system over the past months. To summarise them:

- many customers have no access to the Internet; what solutions to offer them?
- all information has to be provided in English; notice has been taken of the intention to offer access also in other languages, but the language-options the system currently offers are by far not sufficient to enable all our customers to make use of it
- the required data are very complex for the average customer, and very difficult to get hold of
- the system is not very customer-friendly; entries take a long time; each single item has to be registered separately
- the system goes down form time to time, and all the time-consuming entry-work has to be repeated then

As stated in our earlier (December 2003) comment, we understand the need for greater security, but we encounter difficulty in explaining and implementing the complex measures, that the prior notice IFR has introduced for the sending of food products to the USA. All the more because these measures apply to all shipments containing food, independently of the sender being a consumer or a business, and even encompass the sending of food gifts from one private individual to another. A number of small businesses have informed us already, that it will be impossible for them to continue exporting consumer food products to the USA, if they have to comply with the prior notice system.

As we do not foresee to be able to provide, neither by our post office counters, neither by any other means, the assistance most of our customers likely need for sending any food by mail to the USA, we with great emphasis request you to reconsider the prior notice IFR, and to change the prior notice measures in such a way, that at least consumers (including US citizens residing in our country) and small businesses can continue to send food items in accordance with the international mail system that has been developed over the years on the base of the UPU Acts.

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Jointly with the UPU and other UPU-members we are willing to work with you in finding the best possible practical solutions in this matter.

Looking forward to receive your reaction. We also would be pleased to get a confirmation of receipt of this comment. Thank you very much for your co-operation.

Yours sincerely

Tiddo Bresters  
senior consultant international relations

TPG Post BV