From: Szaller Marion [szallerm@posteitaliane.it]
Sent: Friday, May 14, 2004 9:53 AM
To: fdadockets@oc.fda.gov
Cc: Z 665 BN Schreier (E-mail); Troiani Maria Daria;
S.Fischer-Zoll@DeutschePost.de
Subject: Docket No 2002N-0278 - prior notice of imported food

Dear Sirs,

I send you enclosed herewith some relevant comments concerning Poste Italiane's positon in reference to the subject matter for your kind consideration.

Best rergards

Marion Szaller
Manager International Affairs - DELP
Poste Italiane

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<<prior notice.doc>>

EMC 185

Posteitaliane

Divisione Espresso Logistica Pacchi
Servizio Operazioni Internazionali

FDA Division of Dockets Management
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RE: Docket No. 2002N-0278 (prior notice of imported food – reopening of comment period)

Dear Sir, Madam,

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

Poste Italiane is the national public postal operator of Italy. We provide our International mail services in accordance with international treaty law, more specifically the Acts of the Universal Postal Union. One of the basic principles of these Acts is the provision of a universal postal service, which implies the free circulation of postal items throughout the world, through an interconnected single postal territory. By virtue of its UPU membership every UPU member country has to offer the so called universal postal services to every citizen and all businesses and other organisations residing in its country. In order to let this system work the UPU and its members try to limit the conditions with regard to the sending of international mail to an acceptable minimum.

Since their announcement, the prior notice measures have confronted us and our customers, with many questions. 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. Small businesses have informed us, 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. Based on these signals and our own experience we would like to point out the following major deficits of the prior notice IFR:

- for customers having no access to the Internet the system is not workable
- 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 system is not very customer-friendly; entries take a long time; each single item has to be registered separately
- the required data are far too complex for the average customer, and very difficult to get hold of

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Capitale Sociale L.2.561.000.000.000 i.v. Registro delle Imprese di Roma n. 584565/1996

With respect of what outlined above we request you kindly to clarify wtihin short notice what effect 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 into two Entry Types, will produce. Which data exactly have to be provided for which category of mail?
Another aspect we urgently need to know is whether the date of August 12, 2004 is still 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 prenotified and not carrying the pre-notification number provided by FDA will be refused by the competent US authorities.

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.

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

Looking forward to receive your reaction.

Yours sincerely

Marion Szaller
Manager Inernational Affairs – DELP
Poste Italiane