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FDA Division of Dockets Management e-mail: fdadockets@oc.fda.gov

RE: Docket No. 2002N-0278 (prior notice of imported food - reopening of comment period)

Dear Sir / Madam,

We are responding to your invitation to comment on all aspects of the prior notice Interim Final Rule, as published in the Federal Register of $14^{\rm th}$ April 2004.

Royal Mail is the national public postal operator of the United Kingdom. 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 universal postal service to every citizen and all businesses and other organisations residing in its country. In order to ensure this system works the UPU and its members try to limit the conditions with regard to the sending of international mail to an acceptable minimum, and to ensure these work in practice and are capable of being enforced.

We understand and fully support the need for greater security. Since the announcement of the prior notice measures last December we have advised our customers of the FDA prior notification requirements and have been enforcing these at the point of acceptance to our networks. However, we have faced many questions from customers who have encountered difficulty in complying with the complex measures for sending of food products to the US.

These measures apply to all shipments containing food, regardless of whether the sender is a private person or a business. Business

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customers have informed us it is becoming increasingly difficult for them to export consumer food products to the US if they have to comply with the FDA prior notification system.

Based on this feedback and our own experience we would like to point out the following major concerns we have regarding the FDA prior notification procedure:

- Customers having no access to the Internet are disadvantaged.
- The pre notification system is not customer-friendly and entries take a long time.
- The data requirements are too complex for customers and very difficult to determine.
- The system is only in English, and non-English speaking customers are disadvantaged.
- Each item has to be registered separately and there is no facility for obtaining multiple pre-notification numbers, causing great difficulty for businesses.

We have a responsibility to provide our customers with clear and unambiguous advice, and we therefore need to know whether the date of 12^{th} August 2004 still is intended as the date from which the prior notice measure will now be fully enforced by US authorities. The implication being from that date onwards any mail items not having prior notification and not carrying the reference number provided by FDA will be refused entry to the US.

This situation provides us with a potential dilemma, as since $12^{\rm th}$ December 2003 we have been enforcing the FDA requirements with our customers. It is unclear from the information posted on the FDA website at which final date the US authorities will be fully enforcing the FDA rules. Our customers are understandably confused whether they can in the interim send foodstuffs to the US without prior notification and without penalty.

We request you to urgently reconsider the FDA prior notification procedure and consider modifying it in such a way, that at least consumers and small businesses can continue to send food items to the US in accordance with the international mail system that has been developed over the years on the basis of the UPU Acts. Complying with the requirements of FDA prior notification procedure is causing our customers great inconvenience and costing them money. Our customers also include many US citizens, currently either residing in or visiting the UK, who may wish to send food home to friends or family.

We would be happy to work with you, and other UPU members, to

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develop alternative practical solutions to resolve these issues.

We look forward to receiving your response.

Yours sincerely,

Bob Dart

Head of Customs Policy Royal Mail plc