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VICE PRESIDENT, NETWORK OPERATIONS MANAGEMENT



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May 13, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852-0003

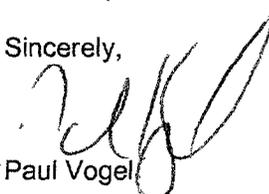
SUBJECT: Docket Number 2002N-0278 - Prior Notice of Imported Food

Recently, the Food and Drug Administration (FDA) reopened the comment period for the interim final rules of Prior Notice through its Federal Register notice of April 14 (Volume 69, Number 72).

The United States Postal Service welcomes this opportunity to provide its comments on the FDA's interim final rules requiring Prior Notice of Imported Food Shipments under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Please find our statement enclosed: "Comments of the United States Postal Service Concerning the Food and Drug Administration's Interim Final Rules on "Prior Notice of Imported Food Shipments" Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (DOCKET No. 2002N-0278)."

Sincerely,


Paul Vogel

Enclosure

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Comments of the United States Postal Service
Concerning the Food and Drug Administration's
Interim Final Rules on "Prior Notice of Imported Food Shipments"
Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
(DOCKET No. 2002N-0278)
May 13, 2004

This statement is submitted by the United States Postal Service (USPS) in response to Food and Drug Administration's (FDA) Federal Register notice of April 14 (Volume 69, Number 72), in which the FDA reopened the comment period on their interim final rules requiring prior notification of imported food authorized under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 Federal Register 58893), Docket No. 2002N - 0278. Section 307 of the Bioterrorism Act requires the Secretary to require by regulation that prior notice be provided for all food imported or being offered for import into the United States.

The USPS wishes to express its concerns with certain aspects of the FDA's interim final regulations for prior notice. We believe FDA's approach for implementation of these regulations will result in serious difficulties, not only for the international mail network at the United States' first ports of entry, but also for the international mailers and the American public we serve. We surmise that the FDA's approach for implementation of these regulations imposes overly demanding requirements on the mailing public, creating a burden which will effectively eliminate the public's ability to send or receive food by mail. More specifically, our observations of the trial stages of implementation of prior notice lead us to believe that that FDA's current approach will result in serious problems in the following areas:

1. The FDA's final interim rule may not have accounted for the single-piece, personal use nature of the majority of mail traffic.
 - In many cases, an individual foreign customer shipping small quantities of food as a gift to another individual would not know the Act's requirements, may not have access to a computer, or may not have the expertise to correctly address all the elements required for prior notice. There may be many mailed packages with no prior notice or inaccurate prior notice information which consequently would have to be identified, seized, verified, decided upon, and then either released, returned or destroyed.

2. The FDA may have imposed unrealistic requirements on the mailing public.
 - The FDA's own estimates have indicated that it would require at least eight hours of training for someone to become familiar with the requirements of the interim final rule. It is not practical to assume that every foreign citizen will be able to obtain this training. Additionally, the FDA's estimates indicate that an individual filing could take up to 23 minutes per item of food contained in a parcel. When one considers the FDA estimate of 2.6 food items per entry, this means that each customer might be required to spend up to an hour simply preparing the information needed for one parcel. Moreover, some of this information may not be readily available to a customer who is mailing back a package with a variety of products purchased in small quantities. An individual mailer may not know how to approach filing prior notice for something like a gift basket which may contain many different types of manufactured items. Furthermore, FDA's Prior Notice System Interface (PNSI) requirement that a mailer determine whether to file a package under "Mail" or "Mail (Non-Commercial Sender)" may lead to even more confusion. Compounding the issue, FDA's Prior Notice system apparently "times out" after 30 minutes; a citizen, inexperienced with FDA's system and not proficient in English, may not be able to accurately complete all the data in time.

3. The USPS has concerns about the impact of the large numbers of individual mailers required to file through FDA's PNSI.
 - We have already observed comments indicating that PNSI response time is quite slow and the system goes down frequently. This can create significant delays for those attempting to file. The USPS believes that the PNSI system will come under even greater strain, once individual mailers start using the system in greater numbers. In addition, the USPS is also concerned that FDA's original estimates of the potential number of entries for PNSI did not adequately account for all of the single-piece package mailings that could require multiple entries per package (either via PNSI or by fax).
4. The FDA's final interim rule may not have adequately accounted for the paper-based nature of mail's content declaration process.
 - The process by which U.S. Customs and Border Protection (CBP) will have to input and verify prior notice confirmation numbers written on customs declarations will be time consuming and demand greater resources from that agency. The FDA and CBP's own procedural document ("Interim Bioterrorism Trade Act Procedures for Trade Partners") recommended against individual manual checks as these could threaten the completion of work during the regular sort-time periods in many Express Courier operations. However, these considerations cannot be extended to mail where individual manual checks are the rule rather than the exception. Consequently, more CBP and FDA work hours will have to be spent simply to verify the prior notice confirmation numbers to determine if these parcels need to be held for inspection. This will also have an impact on service considerations to the American public.
5. The USPS is concerned that the FDA's current intention to include all mailed items as eligible for prior notice requirements (even 'low value' packages less than \$200 and intended for personal use or gifts) will result in an overly burdensome volume of mail packages that will need to be identified, verified, or intercepted by the CBP and then to be held up to 72 hours awaiting FDA inspection.
 - Single-piece, consumer-to-consumer or personal use mailings are an extremely high percentage of international mail traffic profile. Unlike the larger business-to-business cargo shippers, these individual mailers do not have access to sophisticated customs data entry systems or brokers that could help them cope with the procedural requirements that FDA has set out. Consequently, there will be large numbers of mailed packages requiring CBP and FDA attention, simply because the mailers did not have necessary expertise to fully comply with prior notice requirements. These single-piece personal use mailings need to be exempted from prior notice. After all, the interim final rule already exempts certain personal use categories, such as food for personal use accompanying an individual arriving in the United States, or food made by an individual in their personal residence to be mailed as a personal gift.
6. USPS is greatly concerned that the FDA's current plan; to detain mail items with insufficient prior notice data or unaccompanied by prior notice confirmation numbers at the port of arrival (until the prior notice is provided or FDA renders its decision), will represent serious operational difficulties for all agencies concerned.
 - Moreover, the FDA and CBP's longer term plans of returning or destroying items with inadequate or no prior notice data will have adverse impacts on all agencies involved. The following are some of the operational areas of concern:
 - a) The USPS has observed instances when FDA did not have sufficient on-site staffing to cope with the demands of processing items held within a 72-hour period. What new plans and resources would be needed to handle any ensuing backlogs that might build up over a weekend or outside FDA's work-schedule?

- b) There will be a surge of additional costs and paperwork associated with the return or destruction of these additional items even if the FDA opted to simply remove food items from packages. All three agencies' resources will be adversely impacted as they have to cope with the growth in procedures associated with customer notification, package returns, package destructions, or item seizures. Additionally, postal administrations will have to bear the transportation costs for these refused parcels as well as labor costs for handling ensuing claims or inquiries.
 - c) This current plan represents an increased demand on CBP resources, already stretched thin. The USPS' quality of service to the American public will suffer as CBP is required to undertake these additional activities.
 - d) There is a lack of clarity in the current regulations concerning what is to be done with packages where the majority of the contents are not food items (e.g., a package with four souvenir T-shirts and a box of souvenir chocolates). Would this type of package have to be destroyed or returned? What mailing accountability safeguards are in place should the FDA or CBP simply opt to open the package and remove the food?
 - e) There may not be sufficient and appropriate space available at the ports of entry to detain all the food shipments awaiting FDA inspection or FDA and CBP processing. Several sites conducting assessments observed that the volumes of parcels to be detained under current guidelines could quickly exceed available storage capacity.
 - f) Spoilage could become a serious issue, as food in backlogs of mailed packages must wait while CBP or FDA attempt to contact the mailer or the addressee for additional prior notice data clarification.
7. Lastly, FDA's final interim rule needs to distinguish between food imports intended for consumption in the United States and food in mail shipments that simply transit the United States for delivery in a third country. The interim final rules need to exempt foreign-to-foreign transit mail as these items are:
- (a) not intended for U.S. consumption,
 - (b) the transfer of universal service obligation mail between sovereign governmental entities, and
 - (c) from foreign mailers who would not know when to submit the required prior notice data as they do not always know whether their mail dispatches will be transiting the United States.

In conclusion, the USPS supports the goal of the Bioterrorism Act and appreciates the importance of FDA's implementation efforts. We are concerned, however, that the single-piece, personal use nature of mail does not lend itself well to the FDA's current "one-size fits all" approach to improve the security of our nation's food supply. Moreover, the costs and resource implications of FDA applying this type of approach to single-piece, person-to-person, international mailings of manufactured food products may outweigh any perceived benefits.

Not only will FDA's current approach to prior notice force the USPS, FDA, and CBP to dedicate substantial resources simply to attempt effective implementation of these regulations, the approach will give rise to broad range of costs and adverse consequences such as liability concerns, transportation costs, or even sanitation issues, should thousands of low value personal use items (or items in foreign-to-foreign transit-mail dispatches) have to await processing and consequently spoil in U.S. ports of entry. Additionally this approach has already commenced to seriously complicate USPS relationships with other nations' postal administrations (and their customers) who are having difficulties coping with the burdens of these requirements. Finally, even with all these efforts and costs, this approach may not actually achieve the aims of Section 307 of the Bioterrorism Act for improving the security of the nation.

Accordingly, we ask that FDA:

1. Exempt these single-piece, personal use mailings from prior notice requirements.
2. Allow CBP to continue using its time-tested targeting strategies for screening and selection of items from mail shipments arriving at the first port of entry. This approach allows CBP to leverage its experience in screening, detaining, and seizing any illegal food products, agricultural items or other items with restrictions or prohibitions. The CBP and FDA personnel present at these ports of entry already have existing processes in place to resolve any discrepancies with either the mailer, or the addressee.
3. Allow the delivery of mail items containing food, even if the contents are not accompanied by prior notice confirmation numbers, as long as CBP and FDA find no problem with the contents during inspections at the ports of entry.
4. Work in close coordination with CBP and USPS to promote more clarity of understanding on the procedures for packages where the majority of the contents were not food items. These policies will need to be uniformly applied, and must also ensure that proper accountability is provided to the mailers and recipients whose mailed items might have been refused, seized, or destroyed.
5. Extend to those mail shippers that are required by FDA regulations to submit prior notice, the option of filing by fax or mail, if they do not have internet capability or access to a computer. Additionally, consider developing other major language group versions of the PNSI web site, to avoid foreign filers from being timed out, simply because they are not proficient in English.
6. Exempt foreign-to-foreign transit mail from prior notice requirements.

The USPS requests that the FDA take these comments and recommendations into consideration during its review of its interim final rules for Prior Notice of Imported Foods.