



2002 N-0278

May 11, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
U.S.A.

Dear Sir or Madam:

Re: Docket No. 2002N-0278

We are writing to express our concerns regarding the interpretation of prior notice requirements under the Bioterrorism Act. On April 26<sup>th</sup>, we attended an FDA/BTA seminar in Canada to learn of the latest developments in the implementation of the Bioterrorism Act. During this meeting, your representative, Mr. Kevin V. Murray, Supervisor of the FDA/NYK-DO Buffalo Import Branch stated that it was his understanding that a separate prior notice would be required for each consignee when we make a consolidated shipment and that simply attaching a list of consignees to the entry paperwork will not satisfy the prior notice requirements. Mr. Murray further verified this understanding in an e-mail (see attachment) dated Tuesday, May 4, when he responded to the same question asked by our customs broker, Great Lakes Customs Brokerage Inc.

Our customs broker and Mr. Murray have both recommended we write to you to explain in detail why we feel the proposed changes would be incredibly onerous for everyone in the system. First, our product line is high quality, fresh roasted coffee that we ship directly to small specialty coffee shops across the United States on a "just in time" inventory basis. Twice per week we send a truck over the border with coffee orders for as many as 20 to 30 consignees. Once cleared through customs, the separate orders are dropped off at the FedEx Buffalo terminal for eventual delivery. The average value of each shipment to one consignee is approximately US\$200. In preparing one "Consolidated Shipment" entry form, we hand our customs broker, and ultimately U.S. Customs personnel, one document approximately two to four pages long which has all relevant information attached with respect to the consignees and the products being shipped. If we had to prepare a separate entry and prior notice for each consignee, this would increase the amount of paperwork by 25 fold and significantly increase the processing time required by all involved parties at the border. Our increased costs in both out-of-pocket expenses (higher brokerage fees) and time would have to be passed on to our U.S. customers, who would see a price increase of approximately 15%.

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Therefore, ultimately this new requirement would significantly hurt many U.S. retailers of fine foods and beverages. In effect, these proposed new requirements represent a trade barrier for small business and are comparable to a regressive tax structure.

We ask that you reconsider implementing this “one prior notice for one consignee rule” as we fail to see how this improves the security of the U.S. food supply chain. As matters stand now, the FDA is provided with the names and telephone numbers of each consignee with each shipment that crosses the border. The FDA is capable and has all of the information necessary to contact any of our clients should they believe there is a problem with one of our products. We are more than willing to attach a hard copy of each commercial invoice with each consolidated shipment if the FDA feels this additional information would be helpful.

We would appreciate it if you would give serious consideration to this request. Please feel free to contact the undersigned at Telephone # 905-820-8520 with any questions you may have.

Yours truly,



Jim Gilliland  
U.S. Sales & Distribution

pp. BB

Attachment

**Maria**

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**From:** Angela Wilson [AWilson@glcbi.com]  
**Sent:** Wednesday, May 05, 2004 8:38 AM  
**To:** 'maria@reunionislandcoffee.com'  
**Subject:** FW: various consignees

Maria,

See Kevin's response. Once again not very helpful

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

**From:** JoAnn Allender  
**Sent:** Tuesday, May 04, 2004 4:08 PM  
**To:** Angela Wilson  
**Cc:** Dawne Flammger; Thomas Kopolinski; 'Dave Reed'  
**Subject:** FW: various consignees

Kevin's response

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

**From:** Murray, Kevin V [mailto:KMURRAY@ORA.FDA.GOV]  
**Sent:** Tuesday, May 04, 2004 3:54 PM  
**To:** 'JoAnn Allender'  
**Subject:** RE: various consignees

Hi JoAnn,

It was probably me that said it. As it stands right now, one consignee equals one prior notice. So on a consolidated shipment, if there are multiple consignees, a prior notice would need to be generated for each (times what ever other fields would generate a separate prior notice, i.e. different products, different sizes). We suggested to the audience that they make comment on this as the comment period on the regulations are now open again. Attaching a list of consignees to the entry paper work does not satisfy the prior notice requirements. No prior notice review takes place at the time of crossing. This is all done ahead of time.

Kevin V. Murray  
Supervisor  
FDA/NYK-DO Buffalo Import Branch  
Phone: 716-551-4461 ext.3129  
Fax: 716-551-3813

Preamble of the interim final rule follows:

16. Importer, Owner, Ultimate Consignee (§ 1.281(a)(12), (a)(13), and (a)(14) Proposed as § 1.288(n), (o), and (p))

Under section 801(m)(2)(B)(i) of the FD&C Act, an article of food that is imported or offered for import with inadequate notice may not be delivered to the importer, owner, or consignee. Thus, FDA proposed to require their identities so that FDA can take steps to ensure that food refused admission under section 801(m) of the FD&C Act is not delivered to them illegally. FDA proposed that only one importer, owner, and consignee could be identified for each prior notice.

(Comments) Some comments argue that section 307 of the Bioterrorism Act does not require the prior

notice to identify the importer, owner, or consignee of the article of food that is the subject of the notice. They recommend that this requirement in the proposed rule be eliminated as beyond the scope of the statute and unnecessary for the purposes of section 307 of the Bioterrorism Act. One comment argues that FDA should not require submission of information about the consignee. However, another comment states that the level of detail required is generally consistent with the information submitted by customs brokers acting as agents for importers of record.

(Response) As requested by some of the comments, FDA considered deleting this information or making identity of importer, owner, and ultimate consignee optional. However, section 801(m) of the FD&C Act explicitly prohibits delivery of an article refused under section 801(m) to the importer, owner, or consignee. Section 801(l) of the FD&C Act likewise prohibits delivery of an article of food that has been imported from an unregistered foreign facility that is required to be registered under section 415 of the FD&C Act and 21 CFR part 1, subpart H. If we do not know the identity of these persons, we cannot determine if an article of food that has been refused or placed under hold has been illegally diverted and delivered. Accordingly, we have determined that this information is critical to ensure that we can efficiently enforce the prohibitions in section 801(m) and (l). In requiring this information, FDA is relying on both sections 801(m) and (l) and 701(b) of the FD&C Act.

Moreover, information identifying the importer of record and consignee is currently provided as part of the existing entry process (under OMB control number 0910-0046). Under the interim final rule, the CPB and FDA entry submission may be used to satisfy prior notice. We estimate that 80 percent of prior notices will be submitted through the CPB ABI/ACS entry process. We are concerned that deleting this information or making it optional for prior notice purposes could create considerable confusion about whether the information was still required for entry and admissibility purposes. For FDA, these pieces of information are necessary for administering section 801(a) of the FD&C Act and its implementing regulations, which require that FDA provide notice of sampling and notice of intent to refuse admission to the owner or consignee. Indeed, the identities of consignees and importers of record have long been provided to FDA. Prior to the availability of OASIS, FDA was provided with this information about imported foods on the FDA Form 701 (Ref. 18). In addition to the name and address of the importer of record and the consignee, FDA Form 701 included information such as: entry number and date, bill of lading number, port of lading, country of origin, port of unloading, port of entry, value, container number, vessel name, arrival date, location of lot, date available, contact phone number, broker identification, manufacturer/shipper, quantity, packaging description, and a description of the food including the Food Canning Establishment number. Since the availability of OASIS, all information that has been submitted through the ABI/ACS interface has also included name and address of the importer of record and the ultimate consignee. Those who do not provide entry information electronically through ABI/ACS submit a "paper" entry to CBP and also provide FDA paper notification that includes information on importer and consignee. Some still use the FDA Form 701.

(Comments) One comment asserts that the identity of the consignee is proprietary, implying that it is protected from disclosure to FDA.

(Response) Where consignee information is proprietary, it is likely to be "confidential commercial information" and protected from public disclosure. However, the fact that it is considered "proprietary" is not a bar to requiring it in prior notice and entry submissions.

(Comments) Other comments ask that FDA decrease the burden of providing this information by using the registration number, which FDA could use to obtain the other identity information elements from its databases.

(Response) FDA agrees in part. Although the interim final rule does not require the registration numbers of the importer, owner, or ultimate consignee, the FDA PN System Interface allows for submission of the name of the firm and limited address information (city and country) when a registration number is provided.

(Comments) Other comments seek to decrease the burden by asking FDA to require information regarding the entity submitting the prior notice, which could be the importer, owner, or consignee, but not regarding all three. Another comment concedes that FDA should require the identification of the owner, but that the owner is often the importer or the consignee.

(Response) FDA agrees. The FDA PN System Interface provides the transmitter with the ability to easily repeat information, e.g., the submitter is the same as the importer or the owner is the same as the ultimate consignee. This feature may also be available for submission through ABI/ACS, depending on the specific ABI software used by the customs broker or self-filer. The identity of the owner is only needed if it is not the same as the importer or the ultimate consignee.

(Comments) Several comments state that FDA should be able to communicate its admissibility decisions and decisions about prior notice adequacy with the importer.

(Response) As set out in the interim final rule, in the first instance, the carrier will be notified regarding refusals under section 801(m) of the FD&C Act. Information identifying the importer will allow FDA to followup with the importer and develop procedures for notifying them as well.

(Comments) A comment asks that FDA define "importer" consistently with CBP. Another comment expresses confusion as to the meaning of the term "owner," asking whether the requirement for the owner's identity in the prior notice refers to the owner of the article of food at the time it arrives at the port of arrival.

(Response) FDA believes that the persons affected by this interim final rule will know, in most situations, what entities are referred to by the terms "importer" and "owner" since these terms are commonly used in importation, including the CBP entry process. If experience with this interim final rule indicates confusion regarding these terms, then FDA will issue guidance on them.

Regarding the term, "importer," FDA agrees with the comment. The agency believes this term should be interpreted the same as "importer of record" as that term is used by CBP in regard to the entry of merchandise.

Regarding the term, "owner," FDA agrees that this is the owner of the article of food at the time of arrival. However, if a prior notice is given after the article is refused under section 801(m)(1) of the FD&C Act, then the owner is the owner of the article of food at the time the prior notice is submitted.

(Comments) Comments ask FDA to limit the information required to identify the importer, owner, and consignee to the registration number, which FDA could use to obtain the other identity information elements from its databases. In this way, comments seek to decrease the burden of prior notice submission by avoiding manual entry of addresses. Other comments seek to decrease the burden by asking FDA to require information regarding the entity submitting the prior notice, which could be the importer, owner, or consignee, but not regarding all three.

(Response) The interim final rule does not require the registration number of the importer, owner, or ultimate consignee. However, if a registration number is provided, city and country may be provided instead of the full address.

(Comments) A comment states that the identification of the importer, owner, and consignee could be obtained from AMS.

(Response) Although AMS may contain information concerning the consignee, that information is located in the AMS module of ACS and is not available to FDA, as required under section 801(m) of the FD&C Act, which provides that the information must be submitted to FDA. CBP and FDA have concluded that it is not practical, at this time, to attempt to modify AMS and the ACS/OASIS interface to provide this information to FDA.

(Interim final rule) Section 1.281(a)(12), (a)(13), and (a)(14) of the interim final rule require submission of information that identifies the importer, owner, and ultimate consignee. However, the identification of the importer, owner, and ultimate consignee are not required if the article of food is imported or offered for import for transshipment through the United States under a T&E bond.

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

**From:** JoAnn Allender [mailto:JAllender@glcbi.com]  
**Sent:** Monday, May 03, 2004 11:12 AM  
**To:** 'Kevin Murray (kmurray@ora.fda.gov)'  
**Subject:** various consignees

Kevin,

One of our clients attended an FDA BTA seminar in Canada. They informed us that they were told by FDA that they could not list "various" as consignee and include a list of consignee information as an attachment to the release paperwork because FDA needed to know what product was going to what consignee. Please clarify the proper procedure for clients to follow on consolidated shipments. I could not find any information in Prior Notice documents that states that consolidated shipments are not allowed.

Thanks,

JoAnn Allender  
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