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12 July 2004

Division of Dockets Management
Food & Drug Administration
5630 Fishers Lane
Room 1061
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Dear Sir/Madam

**PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS RESPONSE ACT
2002: COMMENTS ON PRIOR NOTICE INTERIM FINAL RULE**

**Agency: Food and Drug Administration, HHS
Docket No: 2002N - 0278**

Thank you for extending to July 13, 2004, the comment period on the prior notice interim final rule (Docket No 2002N – 0278). I attach comments from the Scotch Whisky Association and would be grateful if you could take account of their concerns in revising the interim final rule and in the guidance for industry.

Yours sincerely

James

*James Hughes
First Secretary (Agriculture & Trade Policy)*

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THE SCOTCH WHISKY ASSOCIATION

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The Scotch Whisky Association appreciates the further opportunity afforded by the FDA to comment on its requirement for the Prior Notice of imported food shipments under the Bioterrorism legislation.

Accordingly, it requests that the FDA take the following particular comments into consideration.

FOOD FACILITY REGISTRATION NUMBER

While the FDA has assured the confidentiality of registration numbers in its care, there is considerable concern surrounding the difficulties of preserving confidentiality of registration numbers in the course of conducting business.

1. For example, companies are finding that some of their customers ask for the facility registration number to be included on commercial documents such as invoices so that this information is readily available for completion of the Prior Notice.

In order to assist companies in retaining the confidentiality of their registration numbers in the face of pressure from customers and clients for such declarations, the FDA is requested to issue a statement or instruction to the effect that:

- FDA does not require the registration number on commercial documents,
- provision of a registration number on commercial documents will not facilitate clearance by Customs or FDA of the shipment concerned
- FDA recommends that companies reveal this confidential information once only in a formal letter and ensure by all possible means that their customer (distributor/importer/customs broker, whoever) also respects the confidentiality of this information.

Such an official statement from the FDA would assist exporters by substantiating the grounds for their refusal to agree to the registration number being stated on commercial (or any other) documents.

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It is also suggested that the FDA incorporate the above stated information in their Guidance for Industry publication on Prior Notice, 'Questions and Answers', in response to a question along the lines of "How can I, the owner of a food facility, best safeguard the confidentiality of my Food Facility Registration Number in the face of pressure from business associates who request that information on commercial (or other) documents?"

2. An area of difficulty that is possibly connected with the situation described in point 1, above or that may be facilitated by other vulnerable points in the FDA facility registration/prior notice systems, is the reported abusive and misleading declaration of a registration number in a Prior Notice for shipments that are in no way connected with the food facility which actually owns that registration number. This is a real problem for which the FDA has not, as yet, provided a solution.

FDA is requested to address this particular issue as a matter of priority so that it can provide an Answer to the Question "What precautions does the FDA take or advise be taken to protect against the erroneous declaration of a facility registration number in a Prior Notice for a shipment which has nothing to do with the actual owner of that facility number?"

SAMPLES SUBMITTED FOR QUALITY CONTROL AND PURPOSES OTHER THAN CONSUMPTION

Some companies own a facility that is concerned solely with analysis, quality control, and other such activities and that is totally separate from the facility at which the product is produced for consumption. Any samples which emanate from the former facility are not destined for consumption.

Furthermore, if a company has not yet entered into exporting to the United States and has not therefore registered its food facility, it is wholly unreasonable for it to have to register for the sole purpose of sending samples in order to explore whether there is potential business in the market or not.

It is therefore unnecessary and possibly misleading for the FDA to require that a facility in either of these circumstances should be registered as a food facility. Indeed, it could even cause confusion.

Given this background, the FDA is requested to amend the Prior Notice interface in order to incorporate an option that indicates that a registration number is 'not applicable' for shipments that consist of quality control and other samples and allows the submitter/transmitter in such instances to enter 'N/A'.

MERGER OF FDA AND CBP REQUIREMENTS

The prospect of greater integration between the FDA and Customs and Border Protection (CBP) prior notification systems is to be welcomed. As previously stated early in the consultation process on the requirement for Prior Notice of imported food shipments, the harmonisation of and cooperation between the two systems is essential if the potential burden on industry is to be minimised.

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QUESTIONS RELATING TO C-TPAT

It is understood that, to date, participation in the Customs-Trade Partnership against Terrorism (C-TPAT) has been on a voluntary basis and that it has been taken up principally by larger companies which have the resources available to do so. The principal concern in relation to the complex questions that the FDA has asked is whether provisions implemented as a result of this consultation could result in different tiers of treatment according to which set of arrangements are adopted by a company. It would be fair to say that, at this relatively early stage for businesses getting to grips with the Prior Notice arrangements, a degree of caution is inevitable, particularly on behalf of smaller companies.

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9 July 2004

Fax Cover Sheet



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Message:

Docket No : 2002N – 0278

Dear Sir/Madam

I would be grateful if you would take account of the attached comments on the Prior Notice Interim Final Rule.

Yours sincerely

James Hughes