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**CP.COM.060.2004
12/07/2004**

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
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USA

Docket No 2002N -0278

Introduction

The European spirits industry appreciates the further opportunity to comment on the FDA requirement for the Prior Notice of imported food shipments under the Bioterrorism legislation.

Accordingly, it submits the following particular comments.

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.

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. Another area of difficulty is the incorrect and misleading use of a registration number for shipments that are in no way connected with the food facility which owns that registration number. This is a real problem for which the FDA has not, as yet, provided a solution. This may stem from the situation described in section 1. where companies are pressurised by their customers for 'publication' of their registration number or it may be facilitated by other vulnerable points in the system.

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 to protect against the misleading declaration of a registration number in a Prior Notice for a shipment which has nothing to do with the true owner of the facility number?"

Merger of FDA and C-TPAT requirements

1. 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 this requirement, the harmonisation of and cooperation between the two systems is essential if the potential burden on industry is to be minimised.

2. It is understood that, to date, participation in the C-TPAT has been on a voluntary basis and that it has been taken up principally by larger companies with 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.

Samples submitted for quality control and purposes other than consumption

Some companies own a facility concerned solely with the analysis, quality control, and other such activities, that is totally separate from the facility at which the product is produced for consumption. Any samples which emanate from that particular 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 with a view to exploring 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'.