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December 23, 2003

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

Re: Prior Notice of Imported Food; Docket No. 02N-0278

The National Confectioners Association (NCA) appreciates this opportunity to submit comments regarding the Food and Drug Administration's (FDA) interim final rule on prior notice of imports. 68 Fed. Reg. 58,974 (Oct. 10, 2002).

NCA is the not-for-profit trade association representing more than 650 confectionery manufacturers and suppliers in the United States.

NCA commends FDA for publishing an interim final rule that is far more workable than the original proposed rule. By shortening the time frames for submission of prior notice and by reducing the amount of information required to be submitted, the interim final rule reflects the realities of international trade. We hope that FDA will use the final rule to clear up some remaining uncertainties regarding the new prior notice requirement.

1. The final rule should define the "trip number" required to be included in prior notices for articles of food that arrive by truck, bus, or rail.

The interim final rule requires that the prior notice include a "trip number" for food arriving by truck, bus, or rail. 21 C.F.R. § 1.281(a)(17)(iv), (c)(17)(iv). However, the term "trip number" is not defined. It appears to refer to a number that relates to the particular trip or journey rather than the vehicle. NCA requests that FDA provide clarification as to the meaning of this term.

2. FDA should be aware that imported food may, in some cases, have a U.S. manufacturer.

Some confectionery companies ship candy that was manufactured in the United States to China or other foreign countries for packing into gift baskets. The gift baskets are then imported into the United States. In some cases, candies from multiple U.S. manufacturers are packed into the

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same gift basket. Because the candy was manufactured in the United States, the prior notice for the gift basket will indicate a U.S. manufacturing facility and an FDA facility registration number for a domestic facility. If a gift basket includes candies manufactured by multiple U.S. manufacturing facilities, the prior notice will need to include the names, addresses, and registration numbers of those U.S. manufacturing facilities.

NCA is concerned that the ABI/ACS/OASIS system operated by the Bureau of Customs and Border Protection (CBP) and FDA's Prior Notice System Interface will reject a prior notice for imported food that indicates a U.S. manufacturing facility. We request that FDA confirm that a prior notice identifying a U.S. manufacturing facility will not be rejected or flagged. In addition, it is our understanding that the CBP and FDA systems will accept information for only one manufacturing facility. NCA requests that FDA provide guidance regarding how to complete the prior notice for an imported food from multiple manufacturing facilities.

3. Prior notices submitted to FDA should not be available to the public under the Freedom of Information Act.

NCA requests that FDA clarify that prior notices submitted to FDA will not be subject to public disclosure under the Freedom of Information Act (5 U.S.C. § 552 et seq.) (FOIA). Many confectionery manufacturers consider information about their sources of supply to be confidential business information. FDA regulations define "commercial or financial information that is privileged or confidential" and therefore not subject to public disclosure as "valuable data or information which is used in one's business and is of a type customarily held in strict confidence." 21 C.F.R. § 20.61(b). NCA believes that prior notice information will often meet this definition.

It is worth noting that the Bioterrorism Act prohibits FDA from disclosing information revealing the identity or location of a registered facility, and most prior notices will include information identifying the imported food's manufacturing facility (and possibly also the shipping facility). 21 U.S.C. § 350d(a)(4). We also note that Bureau of Customs and Border Protection regulations permit public disclosure of advance cargo information only if the owner of the information "expressly agrees in writing to its release." 19 C.F.R. § 103.31a.

NCA is concerned that prior notices, if available to a company's competitors under FOIA, will reveal information that has traditionally been regarded as confidential business information. We request that FDA either remove prior notices from FOIA coverage or develop policies to protect confidential business information contained in prior notices from public disclosure.

4. NCA questions FDA's position that prior notice is required for trade samples accompanying an individual arriving in the United States.

FDA has taken the position that trade samples (*e.g.*, food samples imported for test marketing, research and development, or quality assurance purposes) require prior notice to FDA. This requirement will be very difficult to comply with in certain situations. For example, a confectionery company employee visiting West Africa who wishes to bring back samples of cocoa beans may not have access to a computer or even reliable phone service. An employee who purchases samples at a trade show in Europe may be unable to obtain certain information required in the prior notice (*e.g.*, the manufacturing facility's registration number).

NCA requests that FDA consider creating an exemption from the prior notice requirement for trade samples where it is simply not feasible to provide FDA with prior notice.

We appreciate this opportunity to comment.

Respectfully submitted,

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