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Dockets Management Branch (HFA-305)  
Food & Drug Administration  
5630 Fishers Lane Room 1061  
Rockville, MD 20852

**RE: DOCKET# 2002N-0278**

“Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes”

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There is no mechanism in ACS to disclaim “FD-4” listed products. It is likely that some products entered under HTS classifications designated “FD-4” will not be directed to a food use, and therefore would not meet the definition of food as promulgated under Section 201 (f) of the Food Drug & Cosmetic Act, *to wit*:

(f) “The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

FDA has previously responded to comments as follows:

FDA will consider a product as one that will be used for food if any of the persons involved in importing or offering the product for import (e.g., submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use...If the substance can be used in some applications that make the substance “food” and some that do not, the same principles apply.

Under current entry procedure, articles entered under HTS classifications designated as “FD-4” require prior notice.

As a result, a prior notice confirmation number is required for articles which are not subject to prior notice requirements because these articles may not be reasonably expected to be directed to a food use. Moreover, in order to submit these articles for prior notice, they must be mis-coded with an associated FDA product code designating the articles as food. Therefore, they are entered incorrectly in ACS and incorrectly transmitted to FDA when reported for purposes of determining compliance and admissibility.

To rectify this situation whereby the burden of prior notice is not attached to all importers of products classified in HTS "FD-4" headings, we suggest one of the following remedies:

- 1) Program the ACS system to permit disclaimer of "FD-4" products by importers who demonstrate that their products will not reasonably be expected to be directed to a food use.
- 2) Issue a "blanket" prior notice confirmation number to be used exclusively by importers who demonstrate that their products will not reasonably be expected to be directed to a food use.
- 3) Permit an exemption from prior notice, by importer number, to be recognized in ACS at time of entry transmission, to importers who demonstrate that their products will not reasonably be expected to be directed to a food use.

Respectfully submitted,

W. N. EPSTEIN & CO., INC.

*J. Epstein*

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President