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

Establishment and Maintenance of Records:
(Proposed Rule Docket No. 02N-0277)

Dear Hearing Clerk:

This responds to the Food and Drug Administration's notice of proposed rulemaking published in the Federal Register May 9, 2003 relating to the establishment and maintenance of records pursuant to the Bioterrorism and Response Act of 2002.

This proposed rulemaking sets forth the development and maintenance of records associated with the production and distribution of food in the United States. Since these FDA related records requirements are new, and therefore have no history of use in the food industry, we respectfully request that once the regulation is effective, the FDA enforcement personnel need to be instructed to phase in enforcement of these provisions with nontransporters and transporters, especially as to the critical elements of these records regulations.

Most food manufacturers (nontransporters) have these vendor, customer, and shipping records, as to products received and finished products shipped from their facilities. The scope of information required to be maintained in those records, however, may not be present in a single document required to be available to FDA inspectors in the exact format set forth in the proposed regulation. The agency needs to emphasize that required information may be in different formats and remain in compliance.

Furthermore, as FDA pointed out in the preamble to the proposed rule, in many food plants the traceback of raw materials used in the manufacture of a lot of finished product may be difficult, if commingling of bulk raw materials occurs normally in the facility. In this case, traceback of raw materials used in a specific lot of finished product will be impossible in terms of defining a single lot of raw material comprising a single lot of finished product. In view thereof, FDA needs to specify in the final rule that the inability to traceback specific lots of products may be acceptable where commingling of in-process ingredients is necessary or required as a consequence of normal operations.

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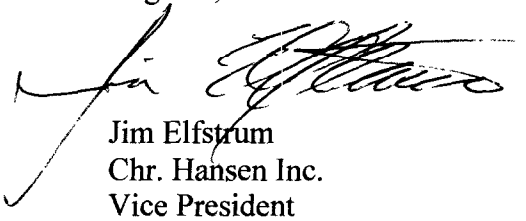
Also, it is noted that under Section 1.337 (a) (2) FDA is requiring the "brand name" and "specific variety" description of the food received by a nontransporter. In the case of food ingredients covered under this provision, the term "specific variety" needs to be clarified, since food ingredients are not referred to in terms of "specific variety". I assume that what is meant by this term as it relates to food ingredients is the "common or usual" name of the food substance. If this is true, FDA needs to more clearly specify same in the final regulation. These comments apply to Section 1.345 (a) (2) and 1.352 (a) (3) where the same reference to "specific variety" is used.

Lastly, under Section 1.361, FDA specifies records availability under the rule of "... 4 hours of a request if the request is made between 8:00 A.M. and 6:00 P.M., Monday through Friday, or within 8 hours of a request if made at any other time." These time frames are not realistic or practical in terms of requesting this information. For example, if FDA requests these records at 7:00 P.M., the firm must provide the requested records by 3:00 A.M. the following morning. A more realistic and practical time frame for such request, in view of most food operations, is 12 hours from the time the request is made, or the next business day, in case this day falls on a weekend or holiday. Since the time period is not specified in the statute, a more reasonable time interval for producing these records is possible.

We appreciate this opportunity to offer comments as to this proposed regulation and look forward to working with the agency as to implementation of the final rule.

Regards,



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