July 8, 2003

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

Re: Establishment and Maintenance of Records under the Public Health Security & Bioterrorism Preparedness and Response Act of 2002; Docket No. 02N-0277; 68 Fed. Reg. 25188 (May 9, 2003)

Dear Sir or Madam:

The Flexible Packaging Association (FPA) appreciates this opportunity to provide comments regarding the Food and Drug Administration's (FDA) proposed rule to implement section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act"). Pursuant to section 306 of the Bioterrorism Act, FDA has published a proposal in the May 9, 2003 *Federal Register* requiring the establishment and maintenance of records.

FPA is the national trade association representing all segments of the flexible packaging industry. Flexible packaging, which combines the best qualities of paper, plastic film, foil, and other packaging materials, is used in packaging food, drugs, and cosmetics, among other consumer products, and also is used in agricultural, industrial, and institutional packaging applications. FPA's members include companies engaged in the manufacture of flexible packaging materials for sale to the users or distributors of such packaging for the production of finished packaging for foods and other consumer products, as well as a host of other products. FPA membership is also open to any operations engaged in the manufacture of materials, equipment, or supplies related to the flexible packaging industry. FPA member companies account for more than half of the 20 billion dollars of flexible packaging produced in the United States each year.

FDA is to be commended for its commitment to food security and its ongoing efforts to implement the Bioterrorism Act. FPA recognizes, in particular, that regulations to

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implement the Act must be promulgated in a relatively short timeframe, and that this task presents numerous challenges. FPA appreciates this opportunity to provide input and offers the following comments concerning the May 9, 2003 recordkeeping proposal.

Recognition of the Functional Barrier Concept

FPA believes strongly that "packaging" is not "food" for purposes of the Bioterrorism Act. Even if FDA disagrees, the Agency is urged to exclude from the recordkeeping obligation all materials that are separated from edible food by a "functional barrier." In other words, FPA believes that, at a minimum, any materials that are separated from edible food by a functional barrier should be regarded as a type of "outer packaging" for which recordkeeping is not required.

The FDA has long recognized the use of a functional barrier in determining what types of materials can be used in a packaging product. If a functional barrier (such as aluminum foil) is present in a packaging laminate, there is no expectation of migration of any material through the functional barrier. Therefore, FPA strongly requests that any materials on the exterior side of a functional barrier be excluded from the recordkeeping regulation. Because there is no expectation of migration of any material through a functional barrier, the likelihood that such materials could be used to adulterate food is extremely remote.

Traceability

Under § 1.337 (a) of the proposal, it is stated that a nontransporter must establish and maintain records to include information reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product. However, in the preamble the FDA recognizes the common practice in food industry to commingle ingredients from different sources prior to incorporating them into a finished product, thus eliminating the ability to identify the specific source of each ingredient used to make finished product. Manufacturers of packaging face the same issues. For instance, during the manufacture of multiple-layer packaging products, it is common to use multiple lots of raw material within a master roll of semi-finished or finished product. An example of this condition would be a paper/foil lamination where one roll of foil and three to four rolls of paper are used in the same production run. In this situation, the lot numbers of the raw materials and the lot numbers of the finished products may be known, but it cannot be determined with precision which lot of the input materials is in an individual roll of finished product.

Another example would be the use of inks and coatings. These materials are mixed in batches for the manufacturing process. During the process, sumps are replenished with material from sequential batches of inks and coatings. Batches of inks and coatings cannot be separated during the manufacturing process. Hence it cannot be determined with certainty exactly which raw material was used on a particular roll of finished product.

Silos are also used in the manufacture of packaging. For example, extrusion resin may be purchased and held in silos until processed into product. The manufacturing processes ensure that materials in the silos are not contaminated through the introduction of foreign material, but do not require that the silo be emptied between each batch of finished product or receipt of additional raw material. Although it may be possible to track the lot numbers and date of receipt of raw material, and infer which lots of incoming raw material are associated with a lot of finished product, it cannot be determined with absolute certainty which exact lots of material are in the finished packaging product.

In light of these industry realities, FPA requests that the Agency in the final rule make clear that, in many instances, it will be impossible to identify the specific source of a material that is held in bulk and that multiple sourcing information in recordkeeping is to be anticipated for raw materials that are held in bulk form.

Records Maintenance in Foreign Facilities

According to § 1.326 of the proposal, foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are subject to recordkeeping requirements, unless the food is further processed (in more than a de minimis manner) in another facility prior to exportation. Many manufacturers of packaging materials, however, may not know the ultimate destination of their products. For example, a facility may supply a primary packaging material to an agent or distributor, who in turn sells the material to another converter for further processing. The converter who further processes the material may export the material to the United States, without the knowledge of the original supplier; if the further processing is of a "de minimis" nature, however, the proposed rule could be interpreted to require the original supplier to maintain records. To address this scenario, FPA asks that foreign facilities be subject to recordkeeping, if at all, only if the facility knows or has reason to know that it is manufacturing/processing, packing, or holding product that is destined for the United States.

FPA also seeks clarification as to the types of activities that will be deemed de minimis. For example, a parent roll of film produced by a foreign facility may be supplied to a foreign distributor/converter who slits and rewinds this roll into small rolls for shipment to food packer/filler in the United States. FPA seeks guidance as to whether this type of slitting/rewinding operation would be considered to be de minimis.

Records Availability

Under the record availability requirement in § 1.361 of the proposal, it states that records and other information must be made available within 8 hours if the request is made at any time other than between 8 am and 6 pm, Monday to Friday. On this basis, for example, the regulation might be interpreted to require records requested at 8 pm to be made available by 4 am. Such an expectation would create an unreasonable burden on facilities, because employees working normal office hours (9 am – 5 pm) typically manage the records. It would be more reasonable and practical to require records to be

supplied in such a circumstance without unjustified delay, but no later than the close of next business day.

Compliance Dates

In proposed § 1.368, additional time is provided for "small and very small businesses" to come into compliance with the regulation. FPA seeks clarification as to whether the size of the "businesses" that may qualify for additional compliance time is based upon the size of the entire corporation or the number of employees at a single manufacturing facility.

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FPA looks forward to working cooperatively with the Agency on this proposal and other food security proposals and initiatives. Please call me at (410) 694-0823 if you have any questions or need additional information.

Sincerely,

Ram K Singhal
Director, Regulatory & Government Relations.

Flexible Packaging Association

FAX COVER PAGE

To: Dockets Mgt. Branch HFA-305	From: RAM SINGHAL	
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Subject: Docket No. 02N-0277	Total Number of Pages Including Cover: 5	

attached are Flexible Packaging Association comments on FDA's proposed regulation Establishment & Maintenance of Records, Docket # 02N-0277

Please note that the same comments were also transmitted today as an attachment via E-mail. We are faxing it to be sure that comments are received and docketted, and thus remove any possibility of electronic file dropping out in transmission via E mail

RAM SINGHAL

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