

April 3, 2003



JEN-COAT, INC.
SPECIALTY EXTRUSION COATERS

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

Re: Proposed Regulations for Registration of Food Facilities
FDA Docket No. 02N-0276

Dear Sir or Madam:

I am writing on behalf of Jen-Coat, Inc. to provide comment on the proposed FDA regulations resulting from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Jen-Coat, Inc. is an Extrusion coating, laminating, metallizing and printing company that provides product to consumer flexible packaging, industrial, and medical customers. Many of our products are designed for, and employed in, direct food contact end uses and are manufactured to be compliant with long standing FDA regulations.

Jen-Coat, Inc., as a member company of the American Forest and Paper Association (AF&PA) supports the AF&PA position on the proposed FDA regulations.

1. FDA's proposed inclusion of food packaging and other food contact substances in the definition of "Article of Food" is not consistent with Congressional intent.
2. Inclusion of food packaging and other food contact materials is not consistent with FDA's Food Security Preventive Measures Guidance.
3. Subjecting food packaging and food contact substances and articles to registration will not further the purposes of the Bioterrorism Act.
4. FDA underestimates the burden of the proposed regulation.

I believe the proposal as written is too broad and does not follow Congress's intent. It will impose an unnecessary burden on companies that provide products which contain imported packaging materials which do not come in contact with food.

The regulation appears to be a duplication of FDA's current regulatory effort regarding food contact packaging .

Our current Quality System requires traceability of product for a variety of reasons including the unlikely event of recall due to contamination of food packaging material.

I recommend the registration requirement focus on articles associated with "food for consumption" based upon a realistic assessment of the threat from contamination in food articles as opposed to packaging components which do not come in contact with food.

I also recommend if registration for companies like Jen-Coat, Inc. are required, that the registration process and information needed is simplified. A limited and simplified registration would allow for immediate communication and traceability of product without causing undue burden.

Sincerely,

William Keefe
Quality Assurance Manager
WK/jw

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