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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 Domtar Inc. to provide comment on the proposed FDA regulations resulting from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Domtar is North America's third largest producer of uncoated freesheet paper and a major producer of specialty paper products. We have manufacturing facilities in both the United States and Canada and employ more than 12,500 employees who contribute to an annual sales revenue of approximately \$2.748 billion (U.S. dollars). Domtar Inc. also manufactures wood products and market pulp. We produce approximately 380,000 tons annually of technical and specialty paper products and about 2.78 million tons of paper products overall each year. Many of our specialty paper products are designed for, and employed in, direct food contact end uses and are manufactured to be compliant with long standing FDA regulations.

Domtar 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 would like to provide additional comments on behalf of Domtar Inc.

- The registration requirements are overly burdensome and complex.
- The proposed regulations are a duplication of regulatory effort. FDA has already promulgated regulations that require food contact packaging to be "unadulterated" and contain "no poisonous or deleterious substances".
- Information submitted may not be protected by the Freedom of Information Act (FOIA) when shared with other agencies.
- The requirement to register trade names is unworkable for many of our specialty packaging products. We reference "brand codes" for our products and frequently alter the grade names associated with the brand codes to reflect the customer's desired nomenclature or the specialty product end use.
- Our product mix changes frequently in response to minor requests from our many customers. The requisite additional staffing that would be required to simply keep up with the need to continuously update our registration would be burdensome.

02N-0276

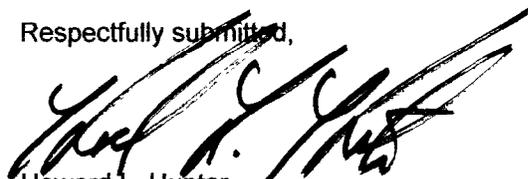
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- The proposed regulations will create a secondary and unintended landslide of customer requests to document that we are a registered facility and in compliance with the proposed FDA regulations. These requests, while not specifically part of the proposed legislation, will occur as our well intended customers scurry to insure the continued safety of the products they buy. We will be compelled to also request similar documentation from our suppliers of components used to manufacture food contact paper products. This will result in a significant burden and we anticipate additional employees will need to be hired simply to deal with this administrative burden, which will yield no additional safety to the food supply of the United States.
- Our products are securely wrapped in tamper evident packaging and identified with a label that has not only package information but enables one to have very rapid traceability of the product through the preceding manufacturing process.

Domtar Inc. recommends that FDA focus the registration requirement on a more narrow definition of "food" to reflect, as AF&PA accurately point out, the Congressional intent to focus the regulatory effort on "food for consumption". Congress did not intend that packaging material be included.

The FDA may want to take an alternate position position on registration only if a more narrow definition of "food", as recommended by AF&PA and Domtar Inc., is not acceptable to the agency. Domtar Inc. recommends that such an alternate position for facilities like ourselves who manufacture food contact paper products be a vastly scaled back requirement for registration. A facility focused registration should include simply information sufficient to enable FDA to contact the facility directly, for example company name, facility name, contact person, contact phone number and contact e-mail address. Such a limited and non-burdensome registration would allow trace-ability of the facility's products through a simple communication while not requiring the Herculean effort the present registration regulation proposal would mandate.

Respectfully submitted,



Howard L. Hunter  
Manager, New Product Development  
Technical and Specialty Papers  
Domtar Representative on the  
AF&PA Food Packaging Safety Subcommittee



Thomas S. Howard  
Director of U. S. Government Relations