RUSSELL D. FEINGOLD
WISCONSIN

506 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224–5323
(202) 224–1280 (TDD)
feingold.senate.gov

COMMITTEE ON THE JUDICIARY
COMMITTEE ON FOREIGN RELATIONS
COMMITTEE ON THE BUDGET
SPECIAL COMMITTEE ON AGING
DEMOCRATIC POLICY COMMITTEE

United States Senate

WASHINGTON, DC 20510–4904

September 12, 2003

Mr. Amit K. Sachdev
Associate Commissioner for Legislative Affairs
Food and Drug Administration
Parklawn Building
5600 Fishers Lane, Room 15-47
Rockville, MD 20857-0002

Dear Mr. Sachdev,

One of my constituents has contacted me regarding the Food and Drug Administration's proposed regulations regarding food packaging.

I have enclosed a copy of my constituent's letter which outlines these concerns. I would appreciate it if you would forward any information you may have concerning this matter to the attention of Matthew Steiner in my Washington office so that I may forward that information to my constituent.

Thank you for your assistance.

Sincerely,

Russell D. Feingold
United States Senator

○ 1600 ASPEN COMMONS
ROOM 100
MIDDLETON, WI 53562
(608) 828–1200
(608) 829–1215 (TDD)

○ 517 EAST WISCONSIN AVENUE
ROOM 408
MILWAUKEE, WI 53202
(414) 276–7282

○ 401 5TH STREET
ROOM 410
WAUSAU, WI 54403
(715) 848–5660

○ 425 STATE STREET
ROOM 225
LA CROSSE, WI 54601
(608) 782–5585

○ 1640 MAIN STREET
GREEN BAY, WI 54302
(920) 465–7508

03-4564

2203353

Green Bay Packaging Inc.

• CORPORATE OFFICE
P.O. BOX 19017
GREEN BAY, WISCONSIN 54307-9017
(920) 433-5111

2003 SEP -2 AM 8:42

August 28, 2003

Congressman Mark Green
700 E. Walnut Street
Green Bay, WI 54301

Dear Congressman Green:

We are writing to express our deep concern regarding three regulatory proposals the Food & Drug Administration (FDA) issued earlier this year under the 2002 Bioterrorism Act. These proposed regulations will impose significant administrative burdens and costs on facilities that manufacture materials that may end up in food packaging without significantly reducing security risk to the food supply. Specifically, these proposals would require facilities that produce any materials ultimately used in packaging food to register annually with the FDA and update documentation monthly, establish and maintain certain tracking records, and provide advance notice of arriving imported materials.

In February 2003, FDA issued two proposals, one of which requires registration by food packaging facilities, and the other prior import notification. In both of these proposals, FDA defined "food" in an exceptionally broad way to include food packaging. Thusly, the proposals apply not only to food processing facilities, but also to plants that manufacture packaging materials for food as well as their component suppliers. In May, FDA issued two additional proposals requiring extensive record-keeping and giving the Agency broad authority to detain suspicious materials. Again, the FDA used the same definition of "food" as in the two prior proposals.

Numerous packaging organizations have filed comments with FDA objecting to the inclusion of facilities that manufacture materials that are used for food packaging in the proposals, citing legislative history contrary to such intent, and detailing the significant administrative work-loads and associated costs that these proposals would impose.

It should be noted that the statutory language addressing the facility registration requirement refers only to "food for consumption." We firmly believe food packaging is not "for consumption," and therefore was not intended to be covered by the registration requirements.

1/3

The legislative history regarding the prior import notice is even clearer, the Conference Report explains that "[t]he Managers intend that the requirements of this section [307] ***should not be construed to apply to packaging materials*** if, at the time of importation, such materials will not be used for, or in contact with, food as defined under section 201 of the [FD&C Act]." H. R. Rept. No. 107-481, 107th Cong., 2d Sess. 137 (May 21, 2002). Rep. Shimkus (R-IL), one of the Managers of the Bioterrorism Act, provided further clarification on the House floor: "Section 307 dealing with prior notice of imported food shipments should not be construed to apply to food packaging materials or other food contact substances if, at the time of importation, they are not used in food." 148 Cong. Rec. E916, (daily ed. May 24, 2002).

In addition to not being mandated by statute, these proposals impose significant administrative burdens on food packaging manufacturers without making the food supply any safer. The proposed registration and recordkeeping provisions exist to allow law enforcement and public health officials to pinpoint the source of contamination after a bioterrorism event has occurred. Given the remote chance that contamination would occur through food packaging and the fact that already existing purchase orders, contracts and transport documentation would allow for easy trace-back, the provisions seem to provide little if any benefit while creating a number of unintended and costly consequences.

FDA is planning to finalize two of the rules by October, 2003, since there is a statutory deadline for the requirements to take effect by December 12, 2003. We understand that FDA, in response to comments already received, is carefully reviewing the statutory language and legislative history regarding Congressional intent. We urge you to contact FDA and express your concern that these provisions are contrary to Congressional intent and will impose significant burdens on the packaging manufacturing industry without reducing risk to the food supply.

Thank you for your consideration in this matter.

Sincerely,

William F. Kress
President & CEO

Cc: Senator Herbert Kohl
Senator Russell Feingold