LAMAR ALEXANDER
TENNESSEE

United States Senate

WASHINGTON, DC 20510

December 5, 2003

Mr. Amit K. Sachdev
Food and Drug Administration
Parklawn Building
5600 Fishers Lane, Room 15-47
Rockville, Maryland 20857

Dear Mr. Sachdev,

I am enclosing comments recently received from one of my constituents, John Zeiser. John is concerned about recent proposals regarding food packaging.

I'd appreciate it if you would contact him directly and provide what information you can. It would also be very helpful if you could copy my office on any reply that you send. Thanks for your assistance.

Sincerely,

Lamar

Southern Champion
Tray, LP

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August 20, 2003 *Visit our website: www.sctray.com*

Buck
FDA

Senator Lamar Alexander
302 Hart Senate Office Building
Washington, DC 20510

Dear Senator Alexander:

I am writing on behalf of Southern Champion Tray, LP to express my concern about three regulatory proposals the Food & Drug Administration (FDA) issued earlier this year under the 2002 Bioterrorism Act. These proposals will impose significant 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 to package food to register annually with the FDA and update the documentation monthly, establish and maintain records, and provide advance notice of arriving imported goods.

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. Thus, 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 record-keeping and giving FDA broad authority to detain suspicious materials. FDA used the same definition of "food" as in the two prior proposals.

Several organizations filed comments with FDA objecting to the inclusion of facilities that make materials that are used for food packaging in the proposals, citing legislative history contrary to such intent, and detailing the significant burdens and costs that these proposals would impose. The statutory language addressing the facility registration requirement refers to "food for consumption." Plainly, food packaging is not "for consumption," and therefore was not intended to be covered by the registration requirements.

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

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 also impose huge burdens and costs on food packaging facilities without making the food supply any safer. The 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 purchase orders, contracts and transport documentation would allow for easy traceback, the provisions seem to provide little if any benefit while creating a number of unintended 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 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 without reducing risk to the food supply.

Thank you for your consideration.

Sincerely,

John M. Zeiser, President/CEO
Southern Champion Tray, LP