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March 5, 2003

Attention: Stuart Shapiro, FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget (OMB)
New Executive Office Building
725 - 17th Street, NW
Room 10235
Washington, D.C. 20503

Re: Docket No. 02N-0276 (Registration)

Dear Mr. Shapiro:

Hansen-Mueller Company welcomes this opportunity to provide comments to the Office of Management and Budget with regard to the U.S. Food and Drug Administration's (FDA) proposed rule to implement the food facility registration provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act" or "Act"). A large importer of various grain products, Hansen-Mueller Company brings oats and other bulk grain agricultural products into the United States principally to meet demand that is not met by U.S. production. Hansen-Mueller Company is a privately owned, U.S. company operating in the grain merchandising, elevator and milling business for 24 years. The primary responsibility of Hansen-Mueller is to handle, process and transport grain and feed products from suppliers to consumers. As a holder of grains for non-propagative use, Hansen-Mueller's grain storage silos and elevators would be required to register with FDA under the proposal.

The Act entrusts FDA with securing the American food supply against acts of intentional contamination, but provides little time for the agency to implement the several provisions designed to fulfill this important mission. Hansen-Mueller understands that FDA is working under stringent time constraints and appreciates the agency's efforts in attempting to implement the Act in record time. It appears, however, that, in the haste to implement the Act's registration provisions, the agency created an over-inclusive proposal that would impose an undue burden on grain and shipping industries, with no practical benefit in preventing and responding to acts of intentional contamination.

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Specifically, the proposal would require owners, operators, or agents in charge of grain storage silos and elevators that are already licensed/approved by the U.S. Department of Agriculture (USDA) to register again with FDA, requiring the submission of much duplicative information. In addition, the proposed rule would ostensibly require the registration of river barges that transport and hold grains. Such requirements would impose an undue paperwork burden on the grain and shipping industries, without practical benefit, and in direct conflict with the goals of the Paperwork Reduction Act of 1995. Hansen-Mueller, therefore, strongly urges FDA to explicitly exempt from the Act's registration requirements grain storage silos and elevators licensed/approved by USDA, as well as grain carriers.

These recommendations are explained in more detail below in answer to certain of the key questions that OMB will be examining as required by the Paperwork Reduction Act. Additional practical concerns raised by the proposal will be addressed separately in Hansen-Mueller's comments to FDA.

I. Registration Of Grain Storage Silos And Elevators Licensed/Approved By USDA Is Not Necessary For The Proper Performance Of FDA's Functions And Serves No Practical Utility

Currently, only those facilities that produce low-acid canned foods are required to register with FDA; thus, the agency cannot be ensured that it has current information on all facilities that produce, pack or hold FDA-regulated products. Congress created the Act's registration requirement to fill this void of information to ensure that the government could identify and locate quickly those entities that are connected with a food product that poses a threat of serious adverse health consequences or death. It is questionable, at best, whether requiring FDA registration of facilities that have already registered with a federal agency would further this goal.

Grain storage silos and elevators licensed under the U.S. Warehouse Act and approved by USDA to store government and price-support grain exemplify this concern. To obtain such approval and a Warehouse Act license, facilities must submit voluminous amounts of information to USDA. Required information includes the facility name and address, manager/supervisor's name and contact information, the names and home addresses of the officers of the corporation, specific physical characteristics of the subject facility, articles of incorporation and financial statements. Submitting less, but redundant, information to FDA would do nothing to further the public policy goal of the registration requirement, namely to ensure that the government has knowledge of and contact information for all food facilities in the event of a terrorist threat to the U.S. food supply.



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In addition, under the Warehouse Act, USDA performs regular, unscheduled inspections of federally licensed grain storage facilities for, among other things, cleanliness and safety. Therefore, USDA, not FDA, would be the most appropriate federal agency to respond to terrorist threats aimed at or affecting such facilities, since USDA is constantly monitoring them. This first-hand knowledge of the licensed facility, along with the voluminous information provided with the applications for the Warehouse Act license and approval to store government and price-support grain, makes additional registration with FDA unnecessary.

Hansen-Mueller, therefore, strongly urges FDA to exempt from the proposed registration requirement federally licensed grain storage silos and elevators approved by USDA to hold government and price-support grain. In the alternative, the agency should, at a minimum, accept submission of the federal license and approvals, in lieu of the proposed FDA registration form. This would minimize significantly the burden of the registration requirement on such facilities. Moreover, the requested change would allow the current Administration to preclude duplicative government regulation at the outset, rather than having to go back and “fix” the problem at some point in the future.

II. FDA Should Clarify That Grain Carriers Do Not Have To Register As Facilities Under The Act

The Bioterrorism Act requires the registration of all facilities that manufacture, process, pack or hold food for consumption in the U.S. The Conference Report accompanying the final legislative language of the Act explicitly states that the registration requirement is not intended to apply to motor carriers that receive, carry, hold, or deliver food “in the usual course of business as carriers.” ^{1/} FDA’s proposal, however, would require river barges that carry and hold grain “in the usual course of business,” to register with FDA, which would impose an enormous burden on both the grain and shipping industries. This conclusion is based on FDA’s proposed definitions of “facility” and “hold.”

Specifically, the proposal would define facilities to include “a mobile facility traveling to multiple locations that . . . holds food for consumption in the U.S.” “Holding” would be defined as the “storage of food.” River barges customarily pick up grain from one location and travel to an alternate location where the barge may store the product in its hull for several months prior to delivering the shipment to the ultimate consignee or purchaser. Thus, under the plain language of the proposal, grain carriers would have to register with FDA as a “mobile facility” that “holds” food.

^{1/} H.R. CONF. REP. NO. 107-481, at 134 (May 21, 2002).



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The impracticality of requiring registration of carriers is clear. River barges and other carriers are constantly on the move and do not have permanent addresses. Moreover, carriers typically do not maintain a constant cargo-hold, such that carriers would have to submit cancellations and updates to their registration with nearly every completed shipment. Thus, to effectuate the clear congressional intent behind the registration provision and avoid undue burden on the grain and shipping industries, as well as FDA, Hansen-Mueller urges the agency to clarify in the final rule that food carriers, including grain carriers that store food "in their usual course of business," are not subject to the Act's registration requirements.

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It is imperative that industry and government undertake all reasonable measures to enhance our homeland security. At the same time, in creating new regulatory requirements, it is imperative that OMB and FDA not lose sight of sound principles of good government, including avoidance of costly, unnecessary duplication.

Thank you for your consideration of our views. We welcome the opportunity to provide any additional information or assistance in ensuring that FDA moves forward in the most efficient and effective manner possible. Along those lines, we are examining the issue of whether Congress intended the Bioterrorism Act's registration provision to apply to animal feed. Although FDA interprets the statute to do so, the legislative history and structure of the statute suggest otherwise. We look forward to discussing this issue in depth with FDA.

Sincerely,

John W. Orr
Hansen-Mueller Company, President

cc: Dockets Management Branch, FDA