American Bakers Association
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December 19, 2003

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

Re: Docket No. 02N-0276; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
68 Federal Register 58893 (October 10, 2003)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. The purpose of this letter is to voice our comments and questions in response to the Agency's interim final rule regarding facility registration.

While ABA appreciates the efforts FDA has made to make this rule workable for industry, there are still several questions and strong concerns that remain. In our comments below, ABA has outlined these concerns for FDA's consideration.

FDA Communications with Industry after October 10, 2003

Communications from FDA to industry from the publication date of the interim final rule on Oct. 10, 2003 through Dec. 12, 2003 were extremely poor. Substantive questions from ABA and its member companies on specific inquiries were unanswered after repeated calls to FDA regarding how industry should comply with this regulation. Calls to the FDA Furls help line, and e-mails to furls@fda.gov with questions regarding if industry should register certain facilities or not were replied to with either a "call back" message or a standard form reply that included no substantive answers to specific critical questions asked by industry. Therefore, companies had to commit the resources of staff and time to err on the side of caution and register as many as 300 additional facilities per baking company.

02N-0276 C180

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While ABA welcomed FDA's "compliance policy guide" regarding facility registration, the Association was disappointed by the delayed issuance date of December 17, 2003, five days after the interim rule implementation date. This delayed information was entirely too late to address legal questions and requirements as to whether companies needed to register certain facilities to comply. Such FDA guidance and communications should have been part of the Oct. 10, 2003 interim final rule on facility registration.

Scope

ABA believes that the inclusion of trade and quality samples falls outside of the intent of the Bioterrorism Act of 2002 for purposes of facility registration. Quality assurance and quality control samples are sent to a small and distinct group of people in a limited quantity. Administrative as well as research and development facilities that receive such samples are highly controlled and do not come in contact with the public. ABA believes in the case of trade and quality samples, the additional registration process would burden both industry and government with additional work to process registration notifications with no added public health benefit.

Additionally, ABA believes that additional clarification is needed on multi-faceted retail establishments that also produce products for other locations. Would these types of facilities need to be registered?

Sharing of Registration Confirmation Numbers and Other Information

ABA has received many questions from its membership on the appropriateness of requiring or sharing with other suppliers their FDA registration confirmation number. Some companies have been requiring this information of their suppliers, but ABA has concerns that this information could be misused or shared with others inappropriately.

Additionally, ABA continues to have the same concerns which were voiced in our previous comments on April 3, 2003 in that the Bioterrorism Act directed that registration information not be subject to disclosure under the Freedom of Information Act (FOIA). However, in FDA's proposal, the agency stated that it will share the filed registration information with other government agencies, provided that the other agencies give written assurance of the information's confidentiality. ABA is concerned about the FOIA status of that sensitive information once it is in the hands of other agencies and of the possible disclosure of that registration information. FDA was not clear in its proposal

why other agencies would be entitled to or need such information. Further clarification was not given in the interim final rule therefore, ABA believes additional clarification and guidance is needed from FDA in this area as it would apply to both other federal agencies and state agencies/officials.

ABA appreciates this opportunity to comment on FDA's food facility registration interim final rule. The Association is hopeful that the detailed concerns outlined will be useful to FDA as the Agency moves forward to finalize policy in this area. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290, Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,

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American Bakers Association