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*PRACTICE WITHIN THE DISTRICT OF COLUMBIA IS LIMITED TO MATTERS AND PROCEEDINGS BEFORE FEDERAL COURTS AND AGENCIES

April 4, 2003

VIA HAND-DELIVERY

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

Re: Docket No. 02N-0276: Responsibility and Liability of U.S. Agents

Dear Sir or Madam:

Olsson, Frank and Weeda, P.C., (OFW) respectfully submits the following comments in response to the Food and Drug Administration's (FDA) proposed regulations implementing the registration requirements of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act"), Pub. Law No. 107-188 (June 12, 2002), which amended the Federal Food, Drug, and Cosmetic Act ("FDC Act"). These comments are specific to the role of U.S. agents as defined in proposed 21 C.F.R. §§ 1.225 and 1.227.

OFW is pleased to have the opportunity to provide comments on the proposed rule. We understand the need for protection of the American food supply, and we commend FDA for its efforts in implementing the Bioterrorism Act.

Upon review of the proposal, we have determined that neither the proposal nor its preamble address the parameters of responsibility and liability for those who act as U.S. agents for foreign entities registering with the FDA pursuant to the requirements of the Bioterrorism Act. For the reasons discussed below, we ask that the final rule clarify that registered agents are responsible only for the accurate, timely transmission of information between FDA and the foreign entity.

Section 305 of the Bioterrorism Act mandates that every foreign facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States must register with FDA by December 12, 2003. The Bioterrorism Act requires that each facility have a U.S. agent and that each facility's registration include the name of that agent. The proposed rule implementing

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the registration requirements of the Bioterrorism Act, 68 Fed. Reg. 5,378, provides that a foreign facility may designate its U.S. agent as its agent in charge for purposes of registration.

The proposed rule would require the U.S. agent to act as a “communications link” between FDA and the foreign facility. 68 Fed. Reg. at 5,418. The proposal explains that FDA will treat representations of the U.S. agent as those of the facility and communications to the U.S. agent as communications to the facility. *Id.*

We understand that it is FDA’s view that U.S. agents should protect themselves from potential liability through carefully worded contractual agreements with foreign facilities. However, this proposition is not addressed in the proposal, and would not provide adequate protection from liability under the FDC Act or 18 U.S.C. § 1001.

We believe that in the limited role of “communications link” between FDA and the foreign facility, a U.S. agent probably should have very limited regulatory responsibilities and liabilities. This responsibility should be limited to the timely, accurate transmission of information between FDA and the foreign facility. U.S. agents should not be exposed to liability beyond that for which they are responsible. The completeness and accuracy of information should be the sole responsibility of the foreign facility. If a foreign facility fails to respond adequately to FDA, despite the best efforts of the U.S. agent, FDA should not attempt to hold the U.S. agent responsible.

Additionally, a U.S. agent should not be held responsible for any other violation of the FDC Act by a foreign facility. While we recognize the importance of protecting the nation’s food supply from adulteration and terrorist activities, we do not believe that there is a basis in existing law for holding U.S. agents vicariously liable for the allegedly illegal acts of foreign facilities.

Our conclusion that a U.S. agent should not be held responsible for violations of the FDC Act committed or caused by the foreign facility is supported by several considerations. First, the Bioterrorism Act added new subsection (dd) to section 301 of the FDC Act, to make the “failure to register” a prohibited act, punishable by injunction or criminal prosecution. There is no comparable prohibited act involving U.S. agents for foreign facilities. Second, by its terms and as interpreted by numerous court decisions, 18 U.S.C. § 1001 would not have any applicability to U.S. agents under ordinary circumstances. Section 1001 prohibits, in relevant part, “knowingly and willfully” making a “materially false” statement to the federal government. Where a U.S. agent accurately relays information between FDA and the foreign facility, there is no basis for imposing liability under 18 U.S.C. § 1001. We request that FDA confirm these conclusions in any final rule.

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Failure to clarify the scope of responsibility and liability of U.S. agents will have a chilling effect on the willingness of U.S. entities to assist FDA in implementing these important provisions of the Bioterrorism Act.

Again, we thank you for the opportunity to comment on the proposed rule. We appreciate the agency's consideration of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard L. Frank", with a long horizontal flourish extending to the right.

Richard L. Frank

RLF:jdm