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May 19, 2003

**BY HAND DELIVERY**

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

Re: Docket No. 02N-0276: Registration Of Food Facilities

Dear Food and Drug Administration:

Olsson, Frank and Weeda, P.C. (OFW) respectfully submits this comment on FDA's proposed rule on the registration of food facilities. Although we recognize that the comment period has closed, we are writing to bring to the agency's attention two significant issues that we have just identified.

As discussed below, we request that FDA notify the U.S. person identified as the U.S. agent of each foreign registrant, thereby providing an easy mechanism to detect – and deter – the possible false identification of a "U.S. agent" when the identified person has not in fact agreed to serve as the registrant's U.S. agent. We further request that FDA confirm in the preamble to the final rule that U.S. agents need not register under the Foreign Agents Registration Act (FARA).

\* \* \*

OFW is concerned that, under the proposed rule, it would be possible for a foreign facility to identify a purported "U.S. agent" when in fact the identified person has not agreed to serve as the facility's U.S. agent. As the proposed rule is written, this submission of false information could occur without detection by either FDA or the U.S. person falsely identified as the "U.S. agent." The false identification of a "U.S. agent" would only be detected when FDA attempted to communicate

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with the foreign facility, using the purported U.S. agent as the communications link, at which time the purported U.S. agent would discover that it in fact has no agency relationship with the foreign facility. The false identification of a purported "U.S. agent" that has not in fact agreed to serve as the U.S. agent would undermine the proposed regulatory scheme, as there would in fact be no ready and reliable communications link for FDA to contact the foreign facility when necessary.

We suggest that FDA establish a procedure whereby any U.S. person identified as the U.S. agent would receive notification of that identification, along with the registrant's identity and address. In this way, any false identification of a purported "U.S. agent" would come to light before FDA needs to use the U.S. agent as a communications link for contacting the foreign facility. We believe it would also act as a deterrent against the false identification of a purported "U.S. agent," when that person has not in fact agreed to serve as U.S. agent.

FDA contemplates that the great majority of registrations will be submitted via the Internet, and that it will confirm registrations and provide the registration number by E-mail. Under these circumstances, the additional burden of notifying the entity identified as the U.S. agent by E-mail should be minimal.

To deter the submission of false information, we request that FDA reiterate in the preamble to the final rule that the submission of false information regarding a U.S. agent to FDA is a criminal offense under 18 U.S.C. § 1001.

\* \* \*

We are concerned that the proposed rule's U.S. agent requirements could be mistakenly interpreted to trigger registration requirements under FARA, 22 U.S.C. § 611 *et seq.*

FARA is a disclosure statute that requires the registration of, and disclosures by, certain agents of foreign principals. In our view, a U.S. agent under the proposed rule would not be required to register under FARA for two reasons:

- In relevant part, FARA applies to an "agent of a foreign principal," defined in relevant part as a person who "within the United States represents the interests of such foreign principal before any agency or official of the Government of the United States," 22 U.S.C. § 611(c)(1)(iv). Under the proposed rule, a U.S. agent would only be performing the ministerial task of serving as the communications link between FDA and the foreign facility and, in some cases, the ministerial task of forwarding registration information to FDA. Those tasks do not involve "represent[ing] the interests of such foreign principal before [FDA]." *See United States v. McGoff*, 831 F.2d 1071, 1074 (D.C. Cir. 1987). A U.S. agent under the proposed rule is not an "agent of a foreign principal" within the meaning of FARA.

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- Second, even if a U.S. agent under the proposed rule is regarded as an “agent of a foreign principal” for purposes of FARA, an exemption from registration is directly on point. Specifically, any person “engaging or agreeing to engage only . . . in private and nonpolitical activities in furtherance of the bona fide trade or commerce of such foreign principal” is exempt from FARA registration. 22 U.S.C. § 613(d). *See Rabinowitz v. Kennedy*, 376 U.S. 605, 609 (1964). There should be no question that the role of a U.S. agent under the proposed rule – serving as a reliable “communications link” – qualifies as private, nonpolitical, mercantile activity.

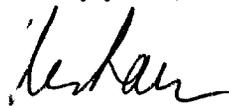
Accordingly, we respectfully request that FDA confirm in the preamble to the final rule that the U.S. agent for a foreign facility is not required to register under FARA.

We note that FARA registration would undermine the proposed U.S. agent requirement by imposing an additional regulatory burden; the cost of complying with the burden would be borne by registered facilities and ultimately would be passed on to consumers. Moreover, if FARA were to apply to U.S. agents under the proposed rule, FARA would likely also apply to – and undermine – other established FDA regulatory schemes which also require the designation of a U.S. agent for a foreign facility, such as drug and device establishment registration and listing, 21 U.S.C. § 360(i).

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We appreciate the agency’s consideration of these comments.

Sincerely yours,



Richard L. Frank

RLF:lac  
cc: Leslye M. Fraser (by Federal Express)