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Via Electronic and US Mail

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

Re: Comments on Interim Final Rule to Implement Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Docket No. 02N-0276, 68 Fed. Reg. 58,894 (October 10, 2003)

Dear Docket Management:

Thank you for this opportunity to comment on the Interim Final Rule (IFR). This firm is acting as an Agent, as required by those rules at 21 CFR § 1.232(d), for many foreign facilities. To date, FDA has said very little about the role of the Agent. This Agent, and other Agents, will be in a much better position to carry out their role properly and conscientiously if FDA can shed more light on the scope of the Agent function.

1. Is FDA serious about requiring 24/7/365 coverage?

The IFR mentions, in passing, that the US Agent must be available at all times. At page 58915 the IFR says "the U.S. Agent needs to be accessible to FDA 24 hours a day, 7 days a week . . . ." But the actual rule does not say this explicitly.

It is easy for an Agent to be available most of the time, but it is very difficult for any individual to be available every minute of every day. If FDA is serious about requiring the Agent (or any other emergency contact) to be available every minute of every day, FDA should say so explicitly, as part of the rule. Subpart H does not currently

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address this point.

For example, if FDA calls one year from today, on a Saturday morning at 9 a.m., and I call back at 10 a.m., is that sufficient? If not, what are the ramifications?

What if I am standing by the phone, fully available, on the same Saturday morning, but FDA sends an urgent email instead of calling? Does the Agent need to monitor both email and the phone on a continuous basis?

What if the Agent is doing the job conscientiously and decides to go hiking for a few hours on the weekend? Does the Agent need to make arrangements for another person to cover the phone? Can the Agent properly delegate its role during this time? And, by contrast, what if the Agent makes no effort to do the job conscientiously; who is liable for such failure and in what way?

To the extent that the Agent role is important, FDA should more clearly explain how a conscientious Agent can properly carry out the Agent role.

2. Confirmations

It is our understanding that, shortly after each foreign facility registration is submitted to FDA, FDA's computer system will send a notification to the designated Agent and to the facility. FDA should clarify. What happens if the facility fails to agree in a timely manner? What happens if the Agent fails to agree in a timely manner? What does FDA plan to do when the designated Agent disagrees, thereby notifying FDA that it does not agree to act as the Agent? In our experience to date, more than one foreign facility has advised FDA that we are serving as Agent, but that facility has not entered into any agreement with this firm. If FDA does not act to prevent this, some foreign facilities will have an incentive to name an Agent in the absence of any agreement for the Agent to carry out this role, and that would seem to be entirely at odds with FDA's goals.

3. Cancellation Fees

The IFR recommends that foreign facilities should have a contract with their US Agent. FDA should make it clear that such contracts should not provide for any

cancellation fee or other penalty if the foreign facility should ever decide to settle with the incumbent Agent and designate a new Agent. If FDA allows cancellation fees, many foreign facilities will simply select a new Agent and submit a new registration in order to avoid paying the cancellation fee. This would lead to redundant registrations and seriously undermine FDA's system. FDA has a strong interest in ensuring that registrations are accurate and regularly updated, and that there is only one active registration per facility. Mandatory cancellation fees are inconsistent with this imperative. FDA has touched upon this at page 58915: "FDA believes that it would be unreasonably complex to allow facilities to have several U.S. agents for purposes of FDA registration, as FDA would then have to determine with which agent to communicate for each product . . . . This would likely hinder communication between FDA and the facility and thereby, thwart a chief purpose of the Bioterrorism Act . . . ." Inasmuch as cancellation fees could hinder a key purpose of the Bioterrorism Act in this way, FDA should not allow them.

Even if FDA is very reluctant to dictate the terms of the relationship between the foreign facility and its Agent, FDA should consider imposing at least minimal safeguards. Otherwise the required "communications link," could be a very weak link indeed. *See* 21 CFR § 1.227(a)(13), and several other references to "communications link" at IFR page 58915 and 58942. As another example of the minimal safeguards discussed above, perhaps FDA should address the manner in which the term "FDA" may or may not be used as part of the Agent's name. With or without disclaimers, a prominent reference to FDA, as part of the Agent's name, could confuse some foreign facilities. To what extent is FDA concerned about the potential for confusion in this regard?

4. Structures containing more than one food business

The IFR seems confusing when it comes to one structure with more than one food operation within. Under the proposed rule, the various food businesses would be separate facilities to the extent that they are under separate *management* (and they store/process food for consumption in the US). Under the IFR, the various food businesses would be separate facilities to the extent that they are under separate *ownership* (and they store/process food for consumption in the US). *See* 21 CFR § 1.227. Does "ownership" refer to the owner of the physical space or ownership of the business within? For example, assume a 3-story industrial warehouse where food is

stored. One company leases the entire first floor for ten years. A second, unrelated company leases floors two and three for twenty years. Is this one facility or two?

By contrast, take the same warehouse, but this time one company owns the entire first floor (in the nature of a condominium). A second, unrelated company owns floors two and three (in the nature of a condominium). Is this one facility or two?

5. Conclusion

Thank you again for this opportunity to comment and seek additional guidance on performing the Agent function properly.

Very truly yours,

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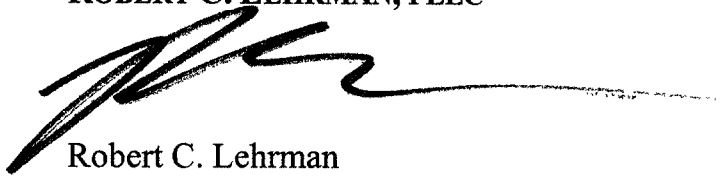

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