



Food and Drug Administration
Office of Policy, Planning, and
Legislation HF-23
5600 Fishers Lane, Rm. 15-74
Rockville, MD 20857

MEMORANDUM OF MEETING

Foreign Establishment Registration
Docket No. 98N-1215

Persons Attending:

For the Canadian Embassy:

Colleen Swords
Minister-Counsellor (Economic and Trade Policy)

Birgit Matthiesen
Commercial Officer

For the Food and Drug Administration:

Walter Batts
Director, International Relations Staff, and
Acting Deputy Commissioner for International and Constituent Relations

Linda Horton
Director, International Agreements Staff

Philip L. Chao
Senior Policy Analyst, Office of Policy, Planning, and Legislation

Matthew Eckel
Associate Chief Counsel for International Affairs, Office of the Chief Counsel

Minna Golden
Associate Director for the Americas, International Relations Staff

Location: Parklawn Building, Room 14-74
Time: 10:00-11:00 a.m.

98N-1215

MMI

Subject: Proposed Rule on Foreign Establishment Registration

Representatives from the Canadian Embassy requested the meeting to discuss the foreign establishment registration proposed rule which appeared in the *Federal Register* on May 14, 1999 (64 FR 26330). The proposed rule would implement section 510(i) of the Federal Food, Drug, and Cosmetic Act which requires, in part, that foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States to register the name and place of business of the establishment and the name of the United States agent for the establishment.

FDA began the meeting by describing the statutory requirement and by summarizing the proposal's main features and the comments to the proposed rule.

The Canadian representatives focused on the United States agent requirement and its application to Canadian device establishments. The Canadian representatives explained that, after submitting its comment, the Government of Canada has revised its position to focus on a possible exemption from the United States agent requirement for Canadian device establishments. [Initially, the Canadian Embassy's comment had sought an exemption from the United States agent requirement for all Canadian establishments.] This change in position reflected the concerns expressed by Canadian device manufacturers as well as Canada's own requirements for foreign drug establishments. The Canadian representatives stated that their goals were: (1) to avoid unnecessary cost to Canadian device firms who export to the United States; (2) to protect the confidentiality of their business information (by not having to share it with an agent); and (3) to maintain direct and prompt communications between Canadian device manufacturers and FDA.

The attendees discussed the United States agent's responsibilities under the proposed rule. The Canadian representatives expressed an interest in the possibility of customs brokers serving as United States agents for Canadian firms. The FDA representatives replied that neither the statute nor the rule required any particular person or entity to serve as the United States agent. The FDA representatives clarified that, as stated in the proposal, the United States agent may be a person or an entity, but must reside or maintain a place of business in the United States. The FDA representatives explained that the proposal reflected the most straightforward interpretation of section 510(i) of the Federal Food, Drug, and Cosmetic Act.

The attendees discussed the United States agent's cost, particularly with respect to the United States agent's liability to FDA, and the desire by Canadian establishments to communicate with FDA directly. FDA explained that the proposed rule does not require all communications to occur through the United States agent and that the agent's obligations under the proposed rule are limited. As for liability issues, the FDA

representatives opined that the liability of the United States agent and the foreign establishment depended on the circumstances. For example, the United States agent might be held liable if it submitted false information to FDA, but might not be held liable if the foreign establishment was responsible for the false information.

Other topics that were discussed briefly included exemptions for small Canadian businesses, different interpretations of section 510(i) of the act so that the United States agent may be located in a foreign country, and consideration of device classifications (so that low risk devices are subject to fewer requirements). The effective date of the final rule was also discussed, and the FDA representatives acknowledged that the preamble to the final rule would address the rule's effective date and registration dates. The preamble to the final rule will also respond to the comments that were submitted to the proposed rule.

The meeting ended shortly before 11:00 a.m.

Date: 17 May 2000

A handwritten signature in cursive script, appearing to read "Philip L. Chao".

Philip L. Chao
Senior Policy Analyst
Office of Policy, Planning, and Legislation