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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 607, and 807

[Docket No. 98N-1215]

Foreign Establishment Registration and Listing; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 60 days the comment period for the proposed rule that appeared in the **Federal Register** of May 14, 1999 (64 FR 26330).

The proposed rule would require foreign establishments whose products are imported or offered for import into the United States to register with FDA and to identify a U.S. agent. The proposal would also describe some of the agent's responsibilities. FDA is taking this action in response to a request from the Canadian Embassy.

DATES: Written comments by (*insert date 60 days after date of publication in the Federal Register*).

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

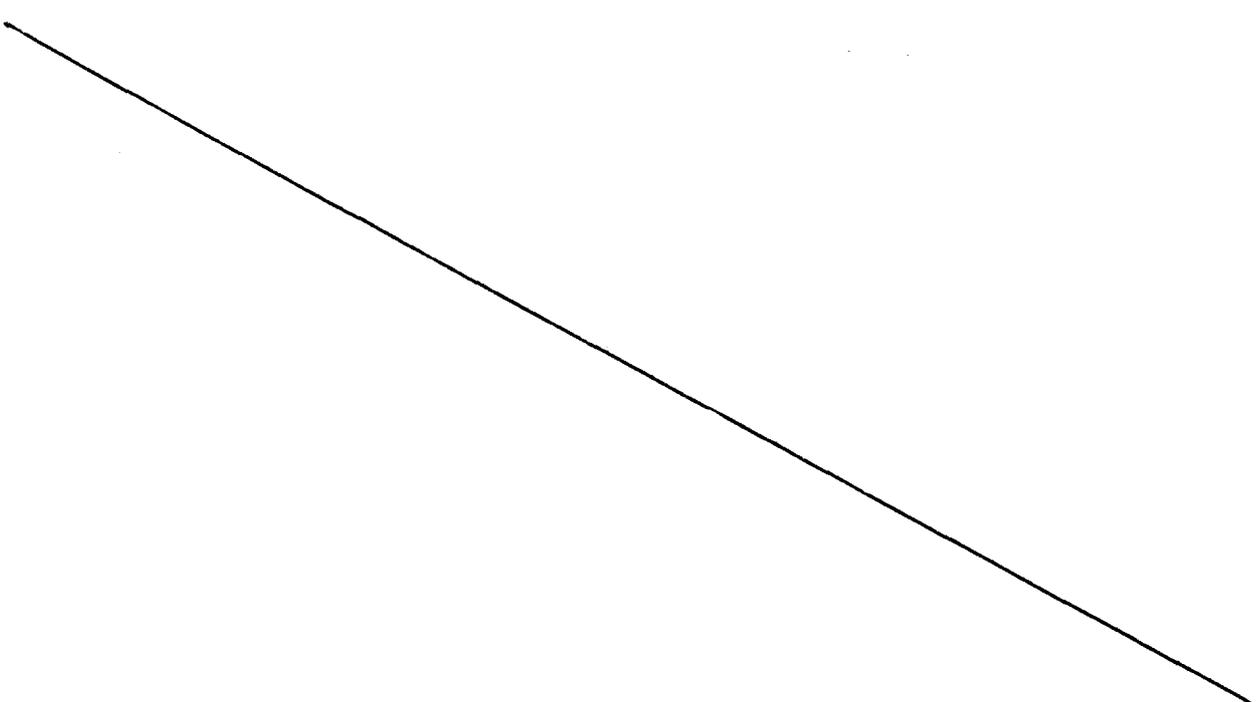
SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 14, 1999 (64 FR 26330), FDA published a proposed rule that would require foreign establishments whose products are imported or offered for import into the United States to register with FDA. The proposal would also require

foreign establishments to identify a U.S. agent and would describe some of the agent's responsibilities. FDA issued the proposed rule in order to implement section 417 of the Food and Drug Administration Modernization Act of 1997. Interested persons were given until July 28, 1999, to comment on the proposed rule.

On July 23, 1999, the Government of Canada requested an extension of the comment period, stating that the proposed requirement could present significant cost and compliance burdens to small and medium-sized Canadian establishments. The Canadian Government requested the extension so that it could: (1) Ensure that affected Canadian establishments are aware of the proposal and (2) prepare informed comments. The requested extension was 60 days.

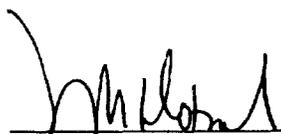
The agency considered the Canadian Government's request and because the request was submitted too late to permit an extension of the comment period the agency is reopening the comment period until (*insert date 60 days after date of publication in the Federal Register*).

Interested persons may submit to the Dockets Management Branch (address above) written comments on the proposed rule. Two copies of any comments are to be submitted, except that



individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the proposed rule and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/1/99
August 1, 1999



Margaret M. Dotzel,
Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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Mark W. Bell