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January 24, 2001

MERCK
Research Laboratories

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

RE: Docket No. 00D-1601
Guidance for Industry and for FDA employees on Import Alert #66-66; Availability

Merck & Co., Inc. is a leading worldwide, human health product company. Merck's corporate strategy -- to discover new medicines through breakthrough research -- encourages us to spend more than $2 Billion annually, on worldwide Research and Development (R & D). Through a combination of the best science and state-of-the-art medicine, Merck's R & D pipeline has produced many of the important pharmaceutical products on the market today.

As an innovative research and development company, Merck is affected by regulations which impact labeling of API's for importation and therefore, we are interested in and qualified to comment on this guidance. The guidance on "Guidance for Industry and for FDA Employees on Import Alert #66-66" is intended to assist in the interpretation of the labeling requirements and exemptions regarding bulk chemicals that can be used as active pharmaceutical ingredients (APIs) for further processing into drug products.

The guidance does not appear to cover exemption allowed under 21CFR 201.122(c) in which the API can be imported to process for marketing if a new drug application or new drug animal application has been submitted but has not yet been approved or disapproved. Clarification is requested.

We appreciate the opportunity to provide comments and trust that these comments will be considered in further development of the guidance.

Sincerely,

Dennis M. Erb

Dennis M. Erb. Ph.D.
Senior Director, Regulatory Liaison

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