Michael C. Elia, Ph.D., DABT Director Regulatory Affairs

February 5, 2001

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Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room. 1061 Rockville, MD 20852 MERCK
Research Laboratories

Dear Sir or Madam:

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## **DOCKET NO. 00N-1669**

## WRITTEN REQUEST TO PARTICIPATE IN ELECTRONIC FILING OF DRUG REGISTRATION AND LISTING INFORMATION

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Pursuant to the Federal Register Notice (Vol. 66, No. 6, pp. 1684-1685) published on Tuesday, January 9, 2001, Merck & Co., Inc. hereby submits to Docket No. 00N-1669 a Written Request to participate in the FDA's pilot project on electronic drug registration and drug listing.

In response to the questions raised in the Notice, the following information is provided:

- Number of Products Currently Listed with the Agency: 378
- Number of Establishments Currently Registered with the Agency: 22
- Type of Products Processed: Human, Biologic, Veterinary
- Processes Performed: Manufacturer, Distributor, Packer, Labeler
- Kinds of Products Processed: Prescription, Over-the-Counter (veterinary only), Active Pharmaceutical Ingredients

If you have any questions or need additional information, please contact Michael C. Elia, PhD, DABT (610-397-3180) or, in my absence, Bonnie J. Goldmann, MD, (610-397-2383).

Sincerely,

M.C. Elia

Michael C. Elia, PhD, DABT Director, Regulatory Affairs

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Federal Express #1

cc: R. Hunter, FDA/CDER (HFD-9), 5600 Fishers Lane, Rockville, MD 20857 Tel. 301-594-6779, e-mail: hunterj @cder.fda.gov. Federal Express #2

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