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Senior Director
Regulatory Affairs

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May 4, 1999

6551 '99 MAY -6 A9:10

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



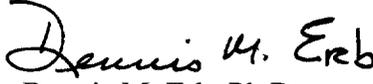
**RE: Docket No. 98D-1168
Draft Guidance for Industry on ANDAs:
Impurities in Drug Products; Availability**

Merck & Co., Inc. is a leading worldwide, human health product company. Through a combination of the best science and state-of-the-art medicine, Merck's R & D pipeline has produced many of the most important pharmaceutical products on the market, today.

The medicines which Merck presents to worldwide health authorities for marketing approval are those that have met the highest technical standards available and those that are able to withstand the most critical regulatory review. Merck supports regulatory oversight of product development that is based on sound scientific principles and good medical judgment. It is in the interests of both sponsors and regulators to see that important therapeutic advances reach patients without unnecessary or unusual delays.

We have reviewed this Proposed guideline and find it consistent with current industry practices. As written, it will not significantly adversely affect our on-going Research and Development programs or manufacturing operations. Should this environment change, we will comment again.

Sincerely,


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

98D-1168

C12

FedEx USA Airbill

Tracking Number

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002052222 9

SPH33

Recipient's Copy

1 From 5/5/99 

Date 5/5/99

Sender's Name Dennis M. Erb, Ph.D. Phone 610) 397-7597

Company MERCK RESEARCH LABORATORIES Dept./Floor/Suite/Room _____

Address 10 SENTRY PKWY BL1-6

City BLUE BELL State PA Zip 19422

2 Your Internal Billing Reference Information _____

3 To Recipient's Name Dockets Mgmt.Branch Phone () _____

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4a Express Package Service Packages under 150 lbs. Delivery commitment may be later in some areas.

FedEx Priority Overnight (Next business morning) **FedEx Standard Overnight** (Next business afternoon) **FedEx 2Day*** (Second business day)

NEW FedEx First Overnight (Earliest next business morning delivery to select locations) (Higher rates apply) *FedEx Letter Rate not available. Minimum charge: One pound FedEx 2Day rate.

4b Express Freight Service Packages over 150 lbs. Delivery commitment may be later in some areas.

FedEx Overnight Freight (Next business day service for any distance) **FedEx 2Day Freight** (Second business-day service for any distance) **FedEx Express Saver Freight** (Up to 3 business-day service based upon distance)

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5 Packaging **FedEx Letter** (Declared value limit \$500) **FedEx Pak** **FedEx Box** **FedEx Tube** **Other Pkg.**

6 Special Handling

Does this shipment contain dangerous goods? No Yes (As per attached Shipper's Declaration) Yes (Shipper's Declaration not required)

Dry Ice (Dry Ice, 9 UN 1845 III, _____ kg, 904 (Dangerous Goods Shipper's Declaration not required)) **Cargo Aircraft Only**

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Total Packages	Total Weight	Total Declared Value*	Total Charges
		\$.00	\$

*When declaring a value higher than \$100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE AND LIMIT OF LIABILITY section for further information.

8 Release Signature

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WGCL 0397
Rev. Date 6/96
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