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June 1, 2000



Dockets Management Branch (HFA-0305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**RE: Docket No. 93D-0139
International Conference on
Harmonizations; Draft Revised
Guidance on Q1A (R) Stability
Testing of New Drug Substances
and Products**

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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.

Merck support regulatory oversight of product development that is based on sound scientific principles and good medical judgment. Regulators must be reasonable, unbiased and efficient when they review the quality, effectiveness and safety of our products. It is in both of our interests to see that important therapeutic advances reach patients without unnecessary or unusual delays.

Merck supports and adheres to the ICH Q1A guidance which was developed for stability testing. We, however, have these following comments for consideration.

GENERAL COMMENTS:

Drug Substances

1. Drug Substances Intended for Storage in a Freezer

"In the absence of an accelerated storage condition for drug substances intended to be stored in a freezer, testing at an elevated temperature (e.g., 5°C ± 3 °C or 25 °C ± 2 °C) on a single batch should be conducted to support use of the drug substance outside of the proposed label storage condition".

Comment:

We would proposed revising to state that "a single batch should be tested to evaluate the impact of short term excursions outside the label storage conditions (such as might occur during shipping)". It is felt that this more appropriately describes the intent of use of the

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drug substance outside of the proposed label storage condition as specific incidence (short term excursions) rather than an undefined events or time outside of the proposed storage condition.

Drug Product

1. Packaging/Containers

We would propose that “For chemical preservatives for which effectiveness is demonstrated with data, preservative testing on stability may not be necessary” be added.

2. Drug Products Intended for Storage in a Freezer

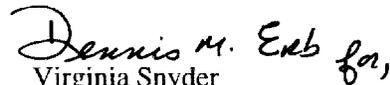
“In the absence of an accelerated storage condition for drug products intended to be stored in a freezer, testing at an elevated temperature (e.g., 5°C \pm 3 °C or 25 °C \pm 2 °C) on a single batch should be conducted to support use of the drug product outside of the proposed label storage condition”.

Comment:

Our comment is the same as proposed above for the drug substance.

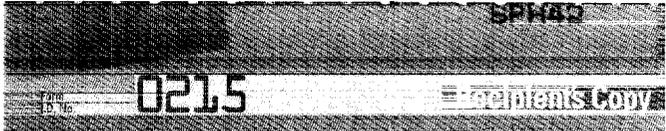
We appreciate the opportunity to provide comments which, from our perspective, will clarify some of the outstanding issues. We trust that these comments will be considered in further development of the proposed rule.

Sincerely,


Virginia Snyder
Manager, Regulatory Affairs

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