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August 20, 2002

4983 '02 AUG -9 A9:15

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



**RE: Docket No. 02D-0231 International Conference on Harmonisation:
Stability Data Package for Registration in Climatic Zones III and IV**

Merck & Co., Inc. is a leading research-driven pharmaceutical products and services company, which discovers, develops, manufactures and markets a broad range of innovative products to improve human health. Through a combination of the best science and state-of-the-art medicine, Merck's Research & Development (R & D) pipeline has produced many of the important pharmaceutical products on the market today.

As a global, innovative R & D company, Merck supports regulatory oversight of product development that is based on sound scientific principles and good medical judgment. Merck Research Laboratories' (MRL) scientists have participated in many ICH discussions about harmonization of worldwide regulatory requirements. Therefore, Merck scientists are interested in, and well qualified to comment on this *Draft Guidance on Q1F Stability Data Package for Registration in Climatic Zones III and IV*, hereafter referred to as *The Draft Guidance*. *The Draft Guidance*, an annex to an ICH guidance entitled *Q1A (R) Stability Testing of New Drug Substances and Products*, hereafter referred to as *Q1A (R)*, defines an approach for broader use of *Q1A (R)* for territories in climatic zones III and IV.

GENERAL COMMENTS:

Merck supports the development of *The Draft Guidance* and, to assist in its further clarification, provides the following comments for your consideration.

The Draft Guidance needs to clearly explain throughout that its requirements pertain to registration of *new* drug substance and products and will not apply retrospectively to product formulations that may already be on the market.

An implementation phase-in period of one-year is recommended. This will allow companies adequate time to make adjustments for on-going studies and to devise appropriate implementation plans for studies in the planning stages.

SPECIFIC COMMENT:

2.3 Cautionary Note on Data Packages for Climatic Zones III and IV states:

If special transportation and storage conditions are identified as being outside the proposed storage criteria, additional study data should be made available, for example up to 3 months at 45-50°C and for Zone IV, 75% relative humidity (RH).

02D-0231

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Merck Comment: This paragraph in this section should be replaced with the following paragraph below. The recommended revision removes the prescriptive and confusing example, but encourages use of appropriate storage conditions in situations where drug substances or products experience excursions in storage conditions beyond those supported by studies conducted according to *The Draft Guidance*:

Recommended Revision: *Where special transportation and storage conditions are identified that are outside the storage conditions specified in this Draft Guidance, additional study data supporting such conditions may need to be made available.*

We appreciate the opportunity to provide comments and trust that these comments will be considered in further development of *The Draft Guidance*.

Sincerely,

A handwritten signature in black ink, appearing to read "David W. Blois for". The signature is fluid and cursive, written over the printed name below.

David W. Blois, Ph.D.
Senior Vice President
Global Regulatory Policy

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