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NOVARTIS

June 24, 2003

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

Comments to: **Draft FDA Guidance "Comparability Protocols—CMC Information", February 2003, Docket 03D-0061**

To whom it may concern:

Novartis Pharmaceuticals Corporation is a world leader in the research and development of products to protect and improve health and well-being. Novartis researches, develops, manufacturers and markets leading innovative prescription drugs used to treat a number of diseases and conditions, including central nervous system disorders, organ transplantation, cardiovascular diseases, dermatological diseases, respiratory disorders, cancer and arthritis. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

As a global pharmaceutical corporation, Novartis is supportive of efforts to improve and to harmonize the technical requirements for registration of pharmaceutical products. We appreciate the opportunity to comment on this guidance in accordance with FDA's Good Guidance practices.

Novartis supports the concept of comparability protocols, based on the successful use of such protocols in past FDA interactions. However, Novartis is concerned that the usefulness of comparability protocols might be dictated by how well they fit into project timelines, when compared to current Prior Approval Supplements done without benefit of comparability protocols. Novartis is also concerned that the Guidance, when finalized, clearly indicate how complete FDA input into the protocols by all involved departments will be obtained.

These points are elaborated and additional comments are provided in the attached tabular format, for ease of FDA use.

These comments are being provided in written form and electronically as directed in the Federal Register Notice.

Novartis appreciates the opportunity to submit these comments and looks forward to continuing to work collaboratively with the Agency on this important initiative to support post-approval CMC changes with appropriately reduced regulatory filing requirements.

Thank you for the opportunity to comment. If you have any questions, please contact me at 862-778-3379 or at e-mail: joan.materna@pharma.novartis.com.

Sincerely,

(signed in original)

✍Joan A. Materna

Global Regulatory CMC