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NOVARTIS

June 26, 2003

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

Comments to: **Draft FDA Guidance "Drug Product—CMC Information", January 2003, Docket 02D-0526**

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 understands the need to update the Guidance for Drug Products to incorporate change necessitated by the Common Technical Document (CTD) and International Conference on Harmonization (ICH) global initiatives supported by the FDA. As a global pharmaceutical corporation, Novartis supports those efforts which lead to greater consistency and quality in global registrations. Novartis is also aware of several ambitious initiatives currently undertaken at FDA to improve drug quality in the 21st century. However, Novartis has some concern that the magnitude of the proposed Guidance revisions as compared with the 1987 FDA Drug Product Guidance , when considered in sum, could be more transparently portrayed to ease evaluation of the proposed changes.

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

02D-0526 C11

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 update the drug product Guidance to incorporate new 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