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May 19, 2004

Division of Dockets Management (HFD-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Comments on International Conference on Harmonisation;
Draft Guidance on E2E Pharmacovigilance Planning
Published on 30 March 2004
Docket No. 2004D-0117**

Dear Sir/Madam:

Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG (NYSE: NVS), a world leader in pharmaceuticals and consumer health. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78,200 people and operate in over 140 countries around the world.

Novartis Pharmaceuticals Corporation researches, develops, manufactures 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.

As one of the world's largest pharmaceutical manufacturers, Novartis has committed extensive resources to the handling of safety information for its investigational and marketed products. The proposals outlined in the ICH E2E draft guideline will significantly impact our global safety handling operations and we appreciate the opportunity to offer comments on this guideline.

I. General Comments:

Novartis agrees with overall goals of the guideline and appreciates the efforts of the ICH to propose a harmonized method and format for summarizing the identified and potential risks of a drug product, and a harmonized structure for Pharmacovigilance plans.

While we recognize the importance of early planning of pharmacovigilance activities and support the need for the development of formalized Pharmacovigilance plans, we are pleased to note that the guideline specifically states that "for products for which no special concerns have arisen, routine pharmacovigilance activities might be considered adequate for the pharmacovigilance plan". Additional actions (e.g., post-marketing safety studies) or enhanced pharmacovigilance efforts should only be necessary in certain limited instances, when an important potential risk is identified either pre- or post-approval. It is important that the guideline acknowledge this important principle.

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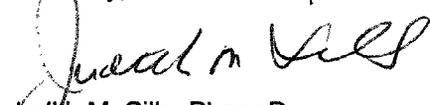
Equally important is the principle that the Pharmacovigilance plan is a 'living' document that may be modified as new information on the safety profile of the product becomes available and as milestones are reached.

Novartis does not agree with the proposal that some ICH regions may require the Pharmacovigilance Plan to include information about the company's organization and practices for conducting pharmacovigilance. The specific reasons for this comment are detailed below.

II. Specific comments:

Section 3.2.2: Routine pharmacovigilance practices. Of particular concern to Novartis is the proposal that some ICH regions might require companies to present within the Pharmacovigilance Plan an overview of the company's organization and practices for conducting pharmacovigilance. We strongly believe that the provision of such information is outside of the scope of the Pharmacovigilance Plan, which is intended to be a product-focused document. A company more properly supplies information about its organization and processes of pharmacovigilance to a Regulator at the time of audits and other inspections. Furthermore, the structure and organization of the Pharmacovigilance department in any company is dynamic and the document would have to be frequent updates to reflect those changes. There is also the concern that if Pharmacovigilance Plans are accessible to the public, proprietary information may be inadvertently released. For all of these reasons, we propose that this section present what is included in 'routine pharmacovigilance practices' (as is currently done in the draft guideline), along with a statement by the company that they are capable of performing all of the appropriate pharmacovigilance tasks.

Sincerely,



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