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September 28, 2006

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

Re: Establishment Registration and Product Listing for Drugs and Biologics-  
[Docket No. 2005N-0403]  
RIN 0910-AA49

Dear Sir/Madam:

The following comments on the proposed rule are submitted on behalf of Novartis pharmaceuticals. 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 more than 78,000 people and operate in over 140 countries around the world.

Novartis Pharmaceuticals corporation 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 publication "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs" released for public comments on Aug 29<sup>th</sup> proposes to amend the regulations governing Drug Establishment Registration and Dug Listing. This proposal describes when and how to register and list and what information must be submitted for registration and listing. In addition, the proposal would make certain changes to the National Drug Code (NDC) system and would require the appropriate NDC number to appear on the labels for drugs subject to the listing requirements. In general we are in agreement with the points made in the proposed rule, however, there are areas that may deserve further clarification, reconsideration or deserve additional discussion. Please see below our comments for your consideration.

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## **Comments for Electronic Drug Listing Proposed Rule**

### **Assignment of NDC Numbers**

1. (Page 87) The proposal requires a human- readable NDC on all labels. This creates an issue for small blisters, ampuls and labels. An adjustment to the text has already been made to accommodate adding a linear barcode. As a result, there is very little space to add a human- readable NDC on the labels. In addition, there are some plants that cannot accommodate such adjustments.
2. (Page 98) Currently we assign the NDC number in advance of approval to facilitate internal systems in preparation for approval. With the proposed rule, at what point can we request an NDC number?
3. (Page 100) In anticipation of marketing needs, it is a common practice that NDC numbers are requested up front for many different packages (e.g., bottles of 30, 60, 90, 100, 500, 1000), but at the end (of approval process) some NDCs are never actually used in the market. Will this have an effect on the assignment of NDC Numbers?
4. (Page 99) A use of numeric and alphabetical characters within the same string (NDC number) would cause difficulties for internal systems and for customers' support, because their systems are configured for numeric values only. The effects would be on our wholesalers' systems, including our direct trading partner's systems, e.g. wholesalers, distributors, warehousing chains, etc.

### **Firm Establishment and Registration**

5. (Page 131) "Foreign establishments only must provide the name, address, telephone and fax numbers, and e-mail addresses of each importer" -- Please clarify what format this information should be submitted in. Also, in situations where there are both foreign and US establishments who should submit the information?
6. (Page 133-135) The term "Content of labeling" is used throughout the document- Please clarify how "Content of labeling" is different from a Package Insert.

### **Drug Listing**

7. (Page 144) **Re: Requirement to provide number of batches and batch size.**



For some products volumes are constantly changing, and lot sizes are variable. Therefore, providing volume data as is suggested by the proposed rule may not be feasible and as such is not preferable. However an estimated yearly volume is possible.

We believe that the proposed rule should address how to Drug List for products for which plant changes the lot size.

8. With regard to Electronic Submission of the Drug Listing, please clarify what format is preferable (i.e., PDF or XML)?

9. Would we need to send Drug Listing on a secure line?

10. (Pages 145, 150-151) Can we still use our own discretion in submitting Drug Listing at the time of a change, or is there a need to do a review every 6 months?

Novartis Pharmaceuticals is grateful for the opportunity to provide comments and offer suggestions and hope that the FDA will consider our response when publishing the final rule for the use of public in the near future.

On behalf of Drug Regulatory Affairs, Labeling Design & Control Department at  
Novartis

Sincerely,

A handwritten signature in cursive script, appearing to read 'S. Madani'.

Soraya Madani PhD  
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