General Correspondence
Comments on FDA Proposed Rule

novo nordisk®

April 1, 2002

Philip L. Chao
Senior Policy Analyst
Department of Health and Human Services
Food and Drug Administration
Room 15-61 (HF-23)
Office of Policy, Planning and Legislation
5600 Fishers Lane
Rockville, MD 20857

RE: Novo Nordisk® Pharmaceuticals, Inc. Response to the FDA Proposed Rule: BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS 61173 Federal Register / Vol. 66, No. 232 / Monday, December 3, 2001

Dear Sir/Madam:

Herein are provided comments on behalf of Novo Nordisk®, Pharmaceuticals, Inc. on the FDA Proposed Rule referenced above.

Novo Nordisk fully supports the Secretary's initiative to reduce medical errors. We recognize that, as stated in the proposed rule, medication errors are a significant cost to the United States. The principle benefit of this proposed rule is intended to be a reduction in the number of medication errors, including reduced mortality and morbidity.

We believe that the ability of a health professional to use a bar code scanner to compare the drug product to a specific patient's regimen would aid significantly in addressing the most common and serious medication errors. As such, we strongly support including information identifying the drug product, such as the National Drug Code number in the bar code.

We are opposed to requiring the inclusion of lot number and expiration date in the bar code at this time. We believe that requiring lot number and expiration date, while providing some added benefits such as possibly tracing a recalled lot of drug product to a specific individual, or providing additional inventory controls would not significantly reduce the occurrence of serious medication errors. Cost considerations for manufacturers related to retooling of packaging lines with new equipment involving new technologies must be weighed against any added benefits.

02N-0204 C26

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If it is determined that additional benefits relating to trace ability or inventory controls are to be pursued, requiring additional information such as lot number and expiration date in bar codes on shipper cartons only, rather than on individual units, may provide those benefits at a substantially lower cost.

If there are any questions, please contact Robert Fischer, Associate Director, Regulatory Affairs at (609) 987-5891.

Sincerely,
NOVO NORDISK PHARMACEUTICALS, INC.

Barry Reit, Ph.D.
Vice President, Regulatory Affairs

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