General Correspondence
Draft Guidance for Industry and FDA Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information

January 3, 2011

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

RE: Docket No. 2010–D–0319

Draft Guidance for Industry and FDA Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information

Dear Sir/Madam:

Novo Nordisk Inc. appreciates the opportunity to provide comments to the above-referenced docket on the Draft Guidance for Industry and FDA Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information.

Novo Nordisk is a pioneer in biotechnology and a world leader in diabetes care and has a leading position within areas such as hemostasis management, growth hormone therapy, and hormone therapy for women. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to our patients, the medical profession, and society.

After reviewing the Draft Guidance for Industry and FDA Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information, we identified several areas which warrant comment, as detailed below.

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Scope of the guidance

In Section I. "Introduction," the draft guidance states that Dear Health Care Provider (DHCP) Letters are correspondence that are usually intended to alert health care providers about "important new information regarding a human drug or biologic," but medical devices are not stated here (line 23). However, in Section V. "Content and Format of DHCP Letters," medical devices are mentioned along with drugs in the recommendations on the content of the letters (line 347). To eliminate potential confusion, we recommend that the language in the guidance be revised to consistently indicate that the document does not apply to medical devices. Footnote 1 (pg. 1) states that CDER and CBER collaborated on the guidance, but it does not appear that CDRH was a party to the guidance. We therefore believe that the guidance is not intended to apply to medical devices.

Addressees

In section V "Content and Format of DHCP Letters," the draft guidance states that the target audience should be all health care providers who not only could prescribe the drug, but who also could dispense or administer the drug. Notably, whereas the draft guidance appears to be intended to convey important prescribing information to prescribers, this expansion of the target audience would seem to require manufacturers to send DHCP letters to non-prescribers, such as pharmacists, who dispense the medication on behalf of the prescriber, and to non-prescribing nurses who routinely administer medications on behalf of the prescriber (lines 196-209). This would require manufacturers to seek out a list of all such non-prescribing HCPs proactively, and to disseminate the DHCP letter to a far larger audience. To avoid this seemingly unintentional but extremely burdensome expansion of the audience, we recommend that the target audience section be rewritten so that it applies to HCP prescribers only.

Assessment of DHCP letter impact

In Section VI "Assessment of the DHCP Letter Impact," the draft guidance recommends that manufacturers "conduct an evaluation of the extent to which the target audience received the DHCP letter and is aware of the information that was communicated in the letter." The guidance further states that manufacturers should evaluate the extent to which a DHCP letter changed the behavior of a target audience, if the letter was intended to impel such changes (lines 376-380). We recommend that FDA expand the guidance to include recommendations on how manufacturers should conduct the evaluations described in this section. Additional guidance would help industry members consistently perform the impact evaluations.

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REMS communication plan DHCP letters

In footnote no. 2 (pg. 1) of the draft guidance, the following explanation is provided on if the guidance applies to DCHP letters that are part of Risk Evaluation and Mitigation Strategy (REMS) communication plans:

> Although not specifically intended for this purpose, the guidance may be used, in appropriate circumstances, to help develop correspondence to meet certain of the communication plan requirements for Risk Evaluation and Mitigation Strategies (REMS) under section 501-1(a)(3) of the Federal Food, Drug, and Cosmetic Act.

Although this footnote suggests that the draft guidance applies to REMS communication plan DCHP letters, we recommend that FDA develop additional guidance devoted to these letters. As described in the points below, some unique issues surround REMS communication plan DCHP letters, and we ask that the Agency consider and address these points in future guidance:

- How would a sponsor make necessary changes to these letters following publication?
- Would it be permissible to submit minor changes to the letters as part of a product's Annual Report?

Submitting DHCP letters to FDA

We realize that the intent of the draft guidance is to improve DHCP letters by providing guidance on when to use DHCP letters, content and format of the letters, and assessment of the impact of the letters. However, FDA has not provided guidance or issued regulations that clearly address the procedures for submitting DHCP letters to the Agency.

We recommend that the Agency provide guidance on submitting DHCP letters, and address issues such as if the letters should be submitted to FDA's MedWatch program, to the FDA division responsible for the product, or submitted to the Division of Drug Marketing, Advertising, and Communications (DDMAC) using Form 2253, "Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use."

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Novo Nordisk fully supports FDA's efforts to provide guidance on and improve DHCP letters. We appreciate your consideration of our comments on the Draft Guidance for Industry and FDA Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information.

Sincerely,

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Novo Nordisk Inc.

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