



General Correspondence SEP -7 A9:54
Comments on FDA's Draft Guidance **novo nordisk®**

September 1, 2005

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

RE: Docket No. 2005D-0122
Draft Guidance for Industry, Investigators, and Reviewers on Exploratory IND Studies

Dear Sir/Madam:

Novo Nordisk Inc. appreciates the opportunity to provide comments to the above-captioned docket on the *Draft Guidance for Industry, Investigators, and Reviewers on Exploratory Investigational New Drugs Studies*. Novo Nordisk is a pioneer in biotechnology and a world leader in diabetes care. The company has the broadest diabetes product portfolio in the industry, including the most advanced products within the area of insulin delivery systems. In addition, Novo Nordisk 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' lives, the medical profession and society.

Novo Nordisk fully supports FDA's initiative to reduce the time and resources expended during early drug development on candidates that are unlikely to succeed. We believe in FDA's approach as outlined in the draft guidance to simplify the preclinical and early clinical development process.

Our comments and questions to this draft guideline are focused on clarification of the validation status of analytical methods used for characterization of drug substance and drug products for explorative IND studies and clinical trials later in development.

2005D-0122

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Comment/Question 1:

Requirement for analytical test methods is given in line 251 as “*A brief description of adequate test methods used to ensure the identity, etc.*” We interpret the term “adequate” to be defined as methods developed using sound scientific experience and where the underlying experiments are documented in laboratory notebooks. Full scale validation according to ICH Q2A is not conducted and would not be required at this state of development of a drug. Is this a correct interpretation?

Comment/Question 2:

Does this draft guideline reflect FDA policy on the extent or degree of the validation of methods for purity, impurity profile and assay for potency (biological) as a drug moves through its development stages? Recognizing that the majority of new compounds will not reach phase III, acceptance of a gradual development from “a brief description of adequate test methods” as described above for exploratory IND trials through to full scale ICH validation for analytical methods for the characterization of drug substances and drug products (including for stability studies) for phase III studies would facilitate drug development and meet the spirit of this new draft guidance.

Comment/Question 3:

Under “Analytical characterization of candidate product” in lines 264-290, we interpret that the degree of characterization, especially for the impurity profile, must be higher when using the representative batch scenario. The interpretation is based on the suggested analytical testing for the representative batch scenario in order to provide the same degree of safety. If this interpretation is correct, larger batches early in development might be more easily justified by a drug manufacturer.

In summary, Novo Nordisk supports FDA’s efforts to streamline the preclinical drug development phase. We would like the Agency to consider our comments to ensure that the validation process of test methods is clearly stated in the final guidance.

Sincerely,

Novo Nordisk Inc.



Mary Ann McElligott, Ph.D.

Associate Vice President, Regulatory Affairs