

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852
USA

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Novo Nordisk

Novo Nordisk A/S

Novo Nordisk Park
2760 Måløv
Denmark

Tel. +45 4444 8888
Fax. +45 4466 3939
<http://www.novo.dk>

A/S Reg. No. 16201

RE: [Docket No. 99D-2635] Draft Guidance for Industry, ANDA's: Blend Uniformity Analysis

Dear Madam or Sir:

Novo Nordisk appreciates the opportunity to comment on the proposed Draft Guidance for Industry on ANDA's Blend Uniformity Analysis. We would like to support the comments made by PDA dated October 26, 1999 both concerning the general comments and the specific suggestions.

We are particularly concerned about the following issues:

- *Problems Associated with Obtaining Representative Samples*

Problems related to taking and handling of a powder sample are of major concern and may inflict a greater variability on the test result than handling of a compressed tablet where the risk of introducing i.e. transfer errors or segregation is largely eliminated.

- *Consideration of industry trends relating to Formulation Issues, Closed Processing And New Technology*

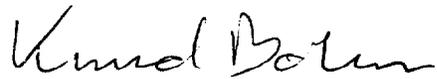
Sampling of a powder bed is a process that does not mimic the process of producing the dose i.e. in the tableting process. Hence Blend Uniformity Analysis does not test any potential segregation occurring after the sampling production and any potential segregation occurring during sampling is not an indication lack of homogeneity. This problem is accentuated when the potency of the Active Pharmaceutical Ingredients increases and the concentration and the dose decreases.

The ideal sample that reflects blending, any segregation and possible reblending and reflects what the patient receives, is the unit dose - that is the tablet. And the tablet is covered by the content uniformity test.

The comments by PDA regarding Closed Processing and New Technology also represent demonstrations of serious drawbacks from the issuance of this guideline i.e. regarding implementation of improved cross contamination control, operator exposure protection and environmental considerations.

Conclusively we strongly agree with PDA's opinion that any guidance should be based on a scientifically supported approach and the solution should include both generic and other drugs.

Yours sincerely,

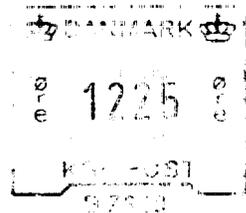
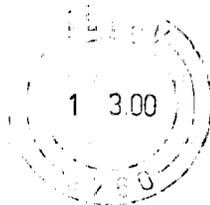
A handwritten signature in black ink that reads "Knud Bohn". The signature is written in a cursive style with a large initial 'K' and a long, sweeping tail on the 'n'.

Knud Bohn

Manager

Solid Dosage Forms Production

Health Care Product Supply



Novo Nordisk A/S

Novo Allé
2880 Bagsværd
Danmark

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(HFA-305)
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Novo Nordisk

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