



Pharma

2524 '00 DEC 28 P4:22

Dockets Management Branch
(HFA-305)
Food and Drug Administration,
5630 Fishers Lane,
rm. 1061
Rockville, MD 20852

USA

Penzberg, November 21, 2000

Re: Draft Guidance for Industry: Analytical Procedures and Methods Validation
[Docket No. 00D-1424]

Dear Sirs,

Please find enclosed our comments to the Draft Guidance for Industry on Analytical Procedures and Methods Validation.

Best regards,

Roche Diagnostics GmbH

ppa.

Dr. K.-H. Sellinger
Head of
Pharmaceutical Biotech Production

i.V.

Dr. I. Krämer
Head of
Regulatory Affairs

(enclosers)

00D-1424

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Roche Diagnostics GmbH

Werk Penzberg
Nonnenwald 2
D-82377 Penzberg
Telefon +49-8856-600
Telefax +49-8856-603896

Sitz der Gesellschaft:
Mannheim
Registergericht Mannheim
HRB 3962
Aufsichtsrat:
Dr. Franz B. Humer, Vorsitzender

Geschäftsführung:
Dr. Jürgen Schwiezer, Vorsitzender
Dr. Manfred Baier, Staffan Ek,
Dr. Marcel Gmünder,
Dr. Volker Pfahlert,
Dr. Werner Schäfer,
Peter-Claus Schiller,
Prof. Dr. Dr. Klaus Strein

Comments on

Draft Guidance for Industry: Analytical Procedures and Methods Validation

by Roche Diagnostics GmbH, Pharmaceutical Biotech Production Penzberg,
November 21 of, 2000

Specific comments:

Line No.

- 436-437 „In cases...“ Delete sentence. Stability indicating properties are part of method development. During method validation they are investigated similar to impurities. It is unacceptable to provide instrument outputs in a registration dossier on a regular basis. It is acceptable to provide such information on request or to review such information during the inspection.
- 765-766 “...the applicant should provide FDA laboratories with the samples within 10 working days”. It is not clear what is understood by samples. In case samples include reagents and standards to perform all assays this requirement is unrealistic, since several standards and reagents (especially like in-house methods to measure host cell protein and the like) will require USDA clearance before they can be imported into the USA. This task cannot be accomplished within 10 working days.



A. Dasa TE-NR

Roche Diagnostics GmbH
Werk Penzberg
Nonnenwald 2
D-82372 Penzberg

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