



ABBOTT

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Division of Dockets Management (HFA-305)
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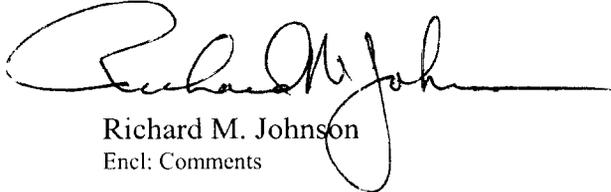
Ref: **Docket No 2003N-0528 – Draft Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms**

To Whom it May Concern:

Abbott is very pleased to have the opportunity to provide comments on the Draft Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms published on February 24, 2005 in the *Federal Register*.

We thank the Food and Drug Administration for your consideration of our comments. Should you have any questions, please contact Kathy Wessberg (tel: 847-938-1264, e-mail: kathy.wessberg@abbott.com).

Sincerely,



Richard M. Johnson
Encl: Comments

2003N-0528

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ABBOTT COMMENTS TO FDA ON

Docket No. 2003N-0528

COMMENTS

General Comments:

Throughout the document reference is made to 21 CFR sections 600 and 211 for biologics and pharmaceuticals. In vitro diagnostics regulated as biologics are not subject to 21 CFR 211. Further, there is no reference made to the in vitro diagnostic medical device regulations. Therefore it can be concluded that in vitro diagnostics which follow 21 CFR 600 but not 21 CFR 211 are excluded from the scope of the guidance. For clarification of expectations, we highly recommend the Scope section clearly state that in vitro diagnostics are not included in the scope of this guidance.

Specific Comments:

II. Scope:

Proposed change:

Include in vitro diagnostics in the third paragraph describing other products this guidance does not apply to.

Change text as highlight in bold:

“This guidance does not apply to allergenic and fungi source material, or therapeutics. **This guidance does not apply to spore-forming microorganisms used in the manufacture of in vitro diagnostics.**”

Reason:

Regulations for in vitro diagnostics are not referenced in the document, they are not specifically stated in the scope, nor are they specifically excluded from the scope, leaving an unclear expectation. Specifically stating they are excluded clarifies the expectation.



ABBOTT COMMENTS TO FDA ON

Docket No. 2003N-0528

IV. Manufacturing with Spore-formers in a dedicated facility

A. Facilities and Equipment

1. Containment

a. Building Construction and Configuration

Proposed change:

Redefine the meaning of "completely walled off".

Currently states: "Being completely walled off means having walls that extend to the roof, having no shared mezzanine or above ceiling spaces with non-dedicated areas and having an independent entrance."

Change text as highlight in bold:

"Being completely walled off means having walls that extend to the **ceiling with properly sealed joints at wall/ceiling intersections, separate HVAC, water drops, sewer line** and having an independent entrance **thereby containing the facility from surrounding areas.**"

Reason:

Walled off as reworded above creates a contained area and is sufficient to prevent cross contamination.

IV. Manufacturing with Spore-formers in a dedicated facility

A. Facilities and Equipment

2. Procedural Control

a. Personnel Gowning and Flows

Proposed change:

Include a complete outer cover change as a personnel gowning option.

Change text as highlight in bold:

"We recommend that personnel who work in manufacturing using spore-formers **complete an outer covering change** or shower and complete a "clean" clothing change prior to entering other areas of the facility or interacting with personnel not directly involved in the manufacturing of spore-formers."

Reason:

Disposable coveralls and boot covers are complete outer covering for employees that can serve as a barrier when working in a spore-former manufacturing facility. Removal of the outer covering before exiting the facility constitutes a complete "clean" clothing change prior to entering other areas of the facility. Therefore it is acceptable to modify the requirement of shower and complete "clean" clothing change to include the option of complete outer covering change only.