



ABBOTT LABORATORIES

Corporate Regulatory and Quality Science

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April 18, 2002

Dockets Management Branch (HFZ -305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

RE: *Medical Devices; Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA [Docket 02D-0028]*

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA draft guidance document "Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays," published in the Federal Register on February 21, 2002 at 67 FR 8031.

Thank you for the opportunity to provide these comments. In general, we found the document helpful in describing the studies and content of premarket notifications for cyclosporine and tacrolimus assays. We have identified a few areas where additional clarification would improve the usefulness of the document.

We suggest clarifying that banked specimens may be used for testing when they are well-characterized and provide sufficient scientific evidence to support product claims. For many studies, the use of prospective specimens, as opposed to retrospective (i.e., banked) specimens, does not add additional value. Therefore, it would be appropriate to conduct such studies using banked specimens.

Under the "Specific Performance Characteristics" section of the guidance document in describing elements of precision and interference studies the phrase "medical decision level(s)" is used. We request greater clarity as to the intent of this phrase. For example, is this intended to refer to toxic, therapeutic, or reportable range limits?

Within the method comparison section, the document states "if samples evaluated in the study included both trough and other times of blood draw relative to drug administration, you should conduct separate analyses for these groups as well." Based on this statement, it appears that studies do not require the inclusion of both peak and trough

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blood draws. We suggest stating this more affirmatively in the document to avoid misinterpretations at the application reviewing stage.

Within the method comparison section, we recommend clarifying that submission of clinical data line listings in the applications is not necessary, as this guidance document describes elements of a 510(k) premarket application. Data should be submitted in the form of summary tables.

Should you have any questions, please contact *April Veoukas* at (847) 937-8197 or by facsimile at (847) 938-3106.

Sincerely,

A handwritten signature in black ink, appearing to read "D L Sporn". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Douglas L. Sporn
Divisional Vice President
Corporate Regulatory Affairs, Abbott Laboratories

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One box must be checked.

No

Yes
See restricted items

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Recipient
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Total Weight

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