



Corporate Regulatory and Quality Science

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April Veoukas
Corporate Regulatory Affairs
D-3QC, AP6C-1
Telephone: (847) 937-8197

100 Abbott Park Road
Abbott Park, Illinois 60064-6091
Facsimile: (847) 938-3106
E-mail: april.veoukas@abbott.com

November 23, 2004

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

RE: *Application User Fees for Combination Products; Draft Guidance for Industry and Food and Drug Administration [Docket 2004D-0410]*

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA draft guidance document "Application User Fees for Combination Products," published in the Federal Register on September 28, 2004 at 69 FR 57942.

Use of the PDUFA "barrier to innovation" waiver provision in the case of two applications for a combination product is appropriate. However, we believe this provision should also apply to those situations in which the sponsor chooses to submit two applications. A sponsor who chooses to avail himself of some benefit of having two applications, such as proprietary data protection or orphan status, should not be forced to forfeit any applicable waiver provided under the PDUFA "barrier to innovation."

Combination products incorporating cutting edge, innovative technologies submitted under two applications do not contain any more data or information than when submitted under a single application, where consultation with another Center is a necessary component of the submission review. Regardless of who decides that two separate applications represent the most appropriate regulatory approach, eligibility for waivers should be the same. The decision to grant a waiver should be based on the innovative merits of the product, not which party determined that submission of two applications is appropriate for the combination product.

Thank you for the opportunity to provide these comments. Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-4422.

Sincerely,

April Veoukas, J.D.
Associate Director, Regulatory Affairs
Corporate Regulatory Affairs & Science
Abbott Laboratories

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