ABBOTT LABORATORIES
Corporate Regulatory and Quality Science

Douglas L. Sporn
Divisional Vice President
GPRD & Life Cycle Management
Telephone: (847) 937-7986

100 Abbott Park Road, AP6C-1
Abbott Park, IL 60064-6091
Facsimile: (847) 938-3106
e-mail: doug.sporn@abbott.com

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

Ref: Docket No. 02D-0449, CVM 200097. Draft Guidance for Industry: The Administrative New Animal Drug Application Process.

Abbott Laboratories commends the FDA-Center for Veterinary Medicine (CVM) on their efforts to provide guidance to industry on the Administrative New Animal Drug Application Process, published in the Federal Register on November 06, 2002.

We are very pleased to have the opportunity to comment on this draft guidance and thank the Agency of your consideration of the following comments.

While this guidance provides a definition and a time frame of 180 days for the review of an Administrative NADA, it appears that it may require not only the completion of target animal safety (TAS) studies, but also clinical efficacy studies prior to completion of the safety technical section review. We believe this could delay the review process. Normally, controlled TAS studies are submitted in advance of clinical efficacy studies. We ask that CVM clarify whether or not clinical efficacy data will be required prior to issuance of a complete letter for the safety technical section. In addition, CVM has not set timelines for review of a technical section. We believe this may lead the agency to take an unlimited amount of time to review each technical section. Therefore, we recommend that CVM communicate their expectation for completing the technical sections review in the final guidance.

Should you have any question, please contact Chauncey Baldwin at (847)-935-1660 or by FAX at (847) 937-7369.

Sincerely,

Douglas L. Sporn

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