



# ABBOTT LABORATORIES

## Corporate Regulatory and Quality Science

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July 3, 2002

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

**RE:** Guidance for Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations  
[Docket 02D-0081]

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA draft guidance document "A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations" published in the Federal Register on April 11, 2002 at 67 FR 17704.

Thank you for the opportunity to provide these comments. We agree with FDA and the Blood Products Advisory Committee's (BPAC) recommendations on an approach to a stepwise decrease in the lower limit of detection specifications for lot-release of HBsAg detection assays used to test blood, blood components, and source plasma donations.

However, as indicated in our communications to FDA since publication of the draft guidance on April 11, 2002, there are important considerations regarding guidance implementation by October 31, 2002. Although newer tests like the ABBOTT PRISM HBsAg assay system have detection capabilities well below 0.5 ng HBsAg/mL, the new tests are not, unfortunately, licensed or being integrated into the workflow at blood/plasma collection and test sites. Completion of workflow studies can take as long as three to six months and implementation by October 31, 2002 would not be achievable even if licensure of new tests were imminent.

Our existing licensed tests that have detection capabilities below 1.0 ng/mL have confidence intervals around the range of mean detection values observed and presented by FDA at the March 15, 2001 BPAC meeting. When these confidence intervals are applied to a mean detection level, the percentage of test kit lots that could meet a 0.5

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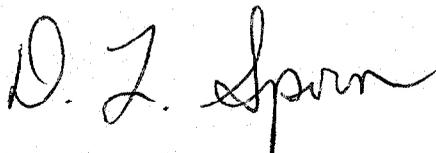
ng/mL lot release standard would be reduced relative to that portrayed at the BPAC meeting.

An analysis of seroconversion data indicated that the proposed change in lot release criteria from our current internal specifications to 0.5 ng/mL would result in an estimated projected yield of 2.2 units of donated blood per year in the U.S. This estimated yield would come at the expense of our ability to consistently supply product to our customers.

We urge FDA to reconsider implementation of the draft guidance until newer tests are available and integrated into blood and plasma testing facilities. Our goal along with FDA is to make sure the draft guidance implementation results in minimal or no disruption in the availability of HBsAg assays for blood establishments, during the implementation of changes in lot-release specifications.

Should you have any questions, please contact Matt Klamrzynski at (847) 937-0970 or by facsimile (847) 938-7192.

Sincerely,

A handwritten signature in black ink, appearing to read "D. L. Sporn". The signature is fluid and cursive, with the first name "D." and last name "Sporn" clearly legible.

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

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