

Corporate Regulatory and Quality Science

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

December 22, 2004

Division of Dockets Management (HFA -305)
Food and Drug Administration2
5630 Fishers Lane - Room 1061
Rockville, MD 20852

RE: *Microbiology Devices; Reclassification of Hepatitis A Virus (HAV) Serological Assays (IgM Antibody, IgG Antibody and Total Antibodies (IgM and IgG)); Proposed rule [Docket 2003P-0564]*

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA proposed rule "Reclassification of Hepatitis A Virus (HAV) Serological Assays (IgM Antibody, IgG Antibody and Total Antibodies (IgM and IgG))" published in the Federal Register on September 30, 2004 at 69 FR 58371.

Thank you for the opportunity to provide these comments. We agree with FDA's identification of Hepatitis A Virus (HAV) serological assays as described under proposed rule 21 CFR § 866.3310(a) as it reflects the clinical use of the assay. In regards to tissue donor screening, which is the last sentence of the proposed description, we recommend FDA modify the wording to reflect the definition of human tissue described in the regulations governing human tissue intended for transplantation, specifically 21 CFR § 1270.3(j). We recommend modifying the sentence as follows:

"These devices are not intended for screening blood or ~~solid or soft tissue~~ donors of human tissue, vascularized organs, or reproductive tissue."

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 & Quality Science, Abbott Laboratories

2003P-0564
Docket # 2003P-0564

C1