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December 23, 2004

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

RE: Docket No. 2003P-0564: Microbiology Devices; Reclassification of Hepatitis A Virus (HAV) Serological Assays (IgM Antibody, IgG Antibody and Total Antibodies (IgM and IgG)); Proposed Rule

Dear Madam/Sir:

AdvaMed appreciates this opportunity to comment on the U.S. Food and Drug Administration's (FDA's) proposed rule to reclassify hepatitis A virus (HAV) serological assays from Class III medical devices to Class II.

AdvaMed, the Advanced Medical Technology Association, represents more than 1,200 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Its members produce nearly 90 percent of the \$75 billion in health technology products consumed yearly in the United States and nearly 50 percent of the \$175 billion purchased around the world annually. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than \$30 million in sales annually.

AdvaMed supports the reclassification of these devices for testing specimens from individuals who have signs or symptoms consistent with acute hepatitis A virus (HAV) infection, or for determining if an individual has been previously infected with HAV. The detection of antibodies to HAV aids in the clinical diagnosis of an acute or past infection by HAV in conjunction with other clinical laboratory findings. HAV was first identified as an etiologic agent of infectious hepatitis in 1973. Since that time, HAV infection has been determined to be primarily self-limiting, with no specific treatment measures for HAV infection. In addition, safe and effective vaccines are now available for HAV. These significant changes in the public health considerations of the epidemiology of HAV infections, and the role of these devices as an aid for the diagnosis of HAV are important considerations in the down-classification of HAV antibody assays.

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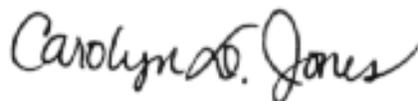
HAV antibody assays have been marketed in the U.S. since 1979, and the long history of their safe and effective use indicates that Class III status is no longer appropriate. FDA reserves Class III for new technology and high risk devices, and, consistent with least burdensome principles, the goal of FDA's classification process is to seek the least restrictive level of regulatory control necessary to ensure the safety and effectiveness of the device. Accordingly, Class II status would be appropriate for HAV antibody assays.

Over the past 25 years of marketing these devices, technological changes have occurred that have improved the performance of these devices. The characteristics of serological assays for HAV antibodies that are necessary for their safe and effective performance are well-established. Currently marketed devices have been shown to be reliable and there are no known direct risks to an individual's health associated with the device.

Finally, there is valid scientific evidence, including widespread laboratory experience, published literature, international standards, voluntary guidances from national and international organizations, and lower classification by regulatory authorities in the European Union and Canada, that demonstrates that general and special controls will provide reasonable assurance of the safety and effectiveness of HAV antibody assays. The special controls draft guidance entitled "Class II Special Controls Guidance Document: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus" will be adequate to address risks of improper patient management associated with this device.

AdvaMed appreciates the opportunity to provide comments. If you have any questions, please do not hesitate to contact me.

Respectfully submitted,



Carolyn D. Jones
Associate Vice President
Technology and Regulatory Affairs