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**Pharmaceutical
Division**

Biological Products

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April 30, 2002

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

Subject: Draft Guidance entitled, "Guidance for Industry: Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV (December 2001)", Docket No. 01D-0584

Dear Sir or Madam,

Bayer Corporation is pleased to provide the following comments on the Food and Drug Administration's (FDA's) draft guidance entitled, "Guidance for Industry: Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV (December 2001)", Docket No. 01D-0584.

1. FDA states that NAT testing technology is not universally available. This is an understatement, since it is well known that licensed testing is available from one source and one system only: testing performed at NGI with their UltraQual PCR methods. The currently licensed test represents a test system rather than a portable test kit and will require a contract for service at a specific business location instead of the purchase of kits for implementation in-house. Information regarding NGI's ability to supply the US plasma industry with HCV and HIV-1 testing services in an accurate and timely manner should be provided along with the guidance document prior to the investment of significant resources into validating and submitting a system by each entity involved in the manufacture of Source Plasma.
 - Does the time-frame indicated in the guidance document take into account potential limitations in the current capacity available to manufacturers for the testing of samples?
 - What if the licensee is unable to accommodate the increased testing volume required ensuring compliance with the guidance document?
 - In the event of system failures at the licensee's test facilities what alternative strategies are allowed under the proposed guidance?
2. Validation studies performed with NGI to meet requirements for a supplement application will be at considerable expense to the Source Plasma manufacturers. FDA should be more specific in the guidance with regard to minimum requirements for test system validations (i.e., number of samples, sample types, analyte levels, validation challenges, etc.), to minimize this cost. Specific requirements for this guidance should be consistent with the language of the "Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2 (December 1999)".

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3. In the Introduction section of the guidance document is the statement "We recommend that you submit pre-approval supplements in accordance with 21 CFR 601.12(b) by June 1, 2002" which we interpret as the date by which you must *submit* your supplement to permit testing by a licensed assay.

In the Implementation section it is stated "Therefore, we recommend that Source Plasma manufacturers submit prior approval supplements to implement HIV-1 and HCV NAT in their establishments by June 1, 2002". We are aware that the June 1, 2002 date is no longer applicable however, this wording could be interpreted as recommending that implementation of HIV-1 and HCV NAT testing should occur by a specified date which would require manufacturers to submit supplements several months in advance of that date to allow FDA time to review and approve the supplements - i.e. misplaced modifier/prepositional phrase. The phrase "by June 1, 2002 (or a specified date)" should be inserted immediately after "...submit prior approval supplements..." since the date refers to the supplement submission date not the implementation of testing date.

Should you have any questions, please contact me or Dr. Mary Ann Lamb at (919) 359-7143.

Sincerely,



Carol M. Moore
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