



Ortho-Clinical Diagnostics

a *Johnson & Johnson* company

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

March 27, 2002

RE: **Docket No. 01D-0584**
Comments on Draft Guidance for Industry: Use of Nucleic Acid Tests on Pooled Samples from Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1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

Dear Sir or Madam:

Ortho-Clinical Diagnostics, Inc. (OCD) is submitting the following comments regarding Docket No. 01D-0584, *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*:

- The Draft Guidance document states that Source Plasma manufacturers must submit a prior approval supplement (PAS) by June 1, 2002 to the Agency in order to implement HIV-1 and HCV NAT in their establishments. We are aware, however, that FDA has advised some fractionators to file a supplement to the final fractionated product license. Clarification is needed for identification of filing responsibilities.
- The Draft Guidance does not identify the contents of the PAS filing. There is no description of the type of validation studies to be performed or the amount of statistical data to be provided. Based on the nature of NAT, one assumes that pooling algorithms, resolution algorithms, sample stability and result reporting should be included in the PAS.
- It is not clear as to whether one PAS can be submitted for use of both HIV-1 and HCV NAT or whether separate filings are need for each assay.
- Donor deferral and release labeling issues are also not addressed in this Draft Guidance as they are in the more recent guidance, *Use of Nucleic Acid Tests*

01D-0584

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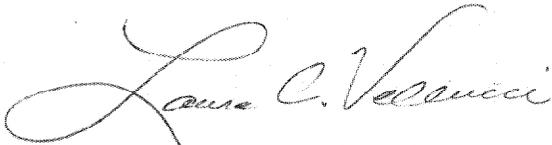
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on Pooled and Individual Samples from Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV.

- Submission of the prior approval supplement by June 1, 2002 is unrealistic considering that the technology is not universally available and establishments need time to implement the technology and collect validation data.
- The Draft Guidance is not clear as to whether the PAS should include a request to eliminate the HIV-p24 testing.

OCD is grateful for the opportunity to provide comments to the Agency regarding this *Draft Guidance for Industry*. We look forward to clarification of these issues in future publications.

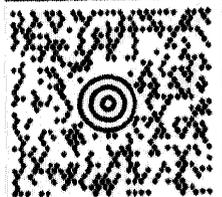
Sincerely,

A handwritten signature in cursive script that reads "Laura C. Vellucci". The signature is written in dark ink and is positioned above the typed name and title.

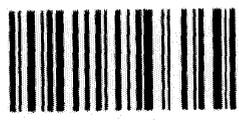
Laura C. Vellucci, Ph.D.
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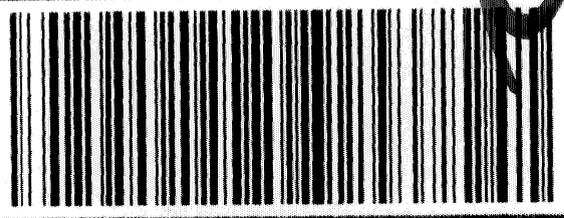


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