



PDA Global Headquarters

4350 East West Highway
Suite 200
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
www.pda.org

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Lee Kirsch, PhD
University of Iowa

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Office of Communication Training
& Manufacturers' Assistance
Center for Biologics Evaluation & Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N
HFM-40
Rockville, MD 20852-1448

Ref.: *Draft Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases – FR Notice September 29, 2006; Vol. 71, No. 189; Docket No. 2006D-0383*

Dear Sir or Madam:

PDA is pleased to provide comments on the *Draft Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases* as published in the Federal Register on September 29, 2006. PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological and device manufacturing and quality. PDA assembled a task force of representatives from the vaccine industry to review and provide specific comment on the Draft Guidance. PDA wishes to thank the FDA for the opportunity to comment on this important document.

PDA is optimistic the publication of this document will provide industry with valuable information and insights into FDA's expectations and requirements for the development and manufacture of prophylactic viral vaccines. Detailed comments are provided in the enclosed table. Comments are identified by topic and section number of the Draft Guidance. The following is a brief overview of two major points the PDA review team believes are important to highlight to the FDA.

Consistency with International Consensus Based Documents

The first point for consideration is related to the harmonization of terminology and requirements. In reviewing the document, the PDA task force identified numerous instances in which the authors have used terminology or made statements contradictory to those found in internationally accepted documents developed and issued under the auspices of the International Conference on Harmonization (ICH). These apparent conflicts with the ICH documents can create serious difficulties for companies seeking to market products in multiple regions. PDA requests that FDA reconcile the current draft guidance document with the other relevant guidance documents wherever possible. Where not possible, PDA requests that FDA provide scientific rationale for the decision. Specific examples may be found in the accompanying table.

Requirements for Stage Specific Testing

The second point for consideration is related to the lack of clarity in the requirements for stage specific testing. While the same test is often performed at multiple stages of manufacturing, the specific study design and the nature of the test article (sample) are different at different stages. This distinction is not entirely clear in the discussion of the test methods. The lack of clarity can lead to unnecessary or inappropriate testing, resulting in data packages that are incomplete and/or difficult to interpret. PDA requests that additional clarity regarding the specific testing required at each stage of manufacture, using a specified test article be articulated in the document.

PDA believes it is of critical importance to ensure there is a clear and shared understanding between FDA and the industry of the concepts outlined in this Draft Guidance and their practical application. PDA believes that all parties will benefit from continued dialogue in this regard and PDA looks forward to continuing to contribute to this discussion.

Sincerely yours,

A handwritten signature in cursive script that reads "Robert B. Myers".

Robert B. Myers
President, PDA