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

Reference: Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up

Docket ID: FDA-1999-D-0081

Dear Sir/Madam:

PDA appreciates FDA's efforts to further clarify its thinking with respect to testing of retroviral vector-based human gene therapy products for replication competent retrovirus during product manufacture and patient follow-up. PDA commends the inclusion of the *Summary of revisions from the 2006 RCR Guidance* section to aid the audience in comprehension of the revised draft. Additionally, the removal of the need to collect and archive patient samples if RCR testing after 1 year provides negative results is a welcome modification.

The PDA does have one proposed change to submit relating to the draft language regarding the reduction or elimination of RCR testing of ex vivo genetically modified cells based on accumulated manufacturing and clinical data. PDA's recommendation is for the final guidance to provide some indication as to how much data (i.e., number of supernatant lots or ex vivo transduced cells) would need to be provided to support the proposed reduction or elimination of testing.

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. Our comments were prepared by a committee of experts with experience in the practice of pharmacy as well as members representing our Biopharmaceutical Advisory Board and Board of Directors.

If there are any questions, please do not hesitate to contact me.

Sincerely,

Richard Johnson
President, PDA

Cc: Tina Morris, PhD, PDA
Josh Eaton, PDA