



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Dr. Frank Hoeren
TGA Laboratories
136 Narrabundah Lane
Symonston
ACT 2609
14 May 2004

Dockets Management Branch (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, rm.
1061, Rockville,
MD 20852
Dear Madame ,Sir:

In reply to:

DrugInfo Comment Form FDA/CDER Site

Subject:

Guidance for Industry
Exocrine Pancreatic
Insufficiency Drug Products –
Submitting NDAs
<http://www.fda.gov/cder/guidance/5064dft.pdf>

My comments are directed to

A. Drug Substance

.... The manufacturing (extraction and purification) process should be validated for its capability to remove and/or inactivate viral agents as recommended in ICH Q5A...
and methods mentioned therein.

I like to draw your attention specifically to

- testing for viruses
- residual DNA

2003 D-0206

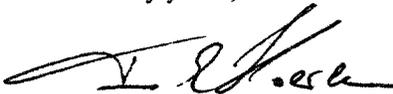
29

In my opinion it is essential to test the final product (plus starting material) for the presence of viruses/ viral nucleic acids and animal derived nucleic acids. Considering that some animal viruses might be able to infect humans. (with the PEP's I consider the risk as low, but anyway).

Emphasis should be on testing for PPV (porcine parvovirus) and/or company should supply validated viral inactivation protocols. (please refer as well to EMEA CPMP/BWP/746/02, "5. Freedom from contamination with viral and TSE agents"; '5.1 Control of viral agents'). In this draft document EMEA specifically includes parenterally administered products!). The document ICH 5A mentioned within the draft does not really address materials derived from animal organs, but discusses viral clearance.

We at TGAL surveyed prescription PEP's via PCR for viral and animal nucleic acids and found positive results for either of the tests in most of the products (preliminary data). At present we are not in a position to make any more statements concerning live virus particles or quantification's. The animal DNA amplified out of the same sample was porcine origin, the viral nucleic acid of porcine parvovirus.

Sincerely yours,



Dr. Frank Hoeren
TGAL
Frank.Hoeren@health.gov.au