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

OFFICERS
Chair:
Vincent Anicetti
Genentech, Inc.
Chair-elect:
John Shabushnig, PhD
Pfizer Inc
Secretary:
Lisa Skeens, PhD
Baxter Healthcare Corporation
Treasurer:
Maik Jornitz
Sartorius Corporation
Immediate Past Chair:
Nikki Mehringer
Eli Lilly and Company
President:
Robert Myers

DIRECTORS
Jennie Allewell
Wyeth Research
Stephen Bellis
IVAX Pharmaceuticals UK
Rebecca Devine, PhD
Regulatory Consultant
Kathleen Greene
Novartis Pharmaceuticals Corp.
Yoshihito Hashimoto, Msc
Chiyoda Corporation
Tim Marten, Dphil
AstraZeneca
Steven Mendivil
Amgen
Amy Scott-Billman
GlaxoSmithKline
Eric Sheinin, PhD
U.S. Pharmacopeia
Gail Sofer
GE Healthcare
Laura Thoma, PharmD
University of Tennessee
Anders Vinther, PhD
CMC Biopharmaceuticals A/S
General Counsel:
Jerome Schaefer, Esq.
O'Brien, Butler, McConihe & Schaefer, P.L.L.C.
Editor, *PDA Journal of Pharmaceutical Science and Technology:*
Lee Kirsch, PhD
University of Iowa

February 20, 2007

Manager,
Drug GMP Inspection Unit,
HPFB Inspectorate,
Graham Spry Building, A.L. #2002B,
250 Lanark Avenue,
Ottawa, Ontario, K1A 0K9

REF: PROPOSAL for REVISIONS to CANADIAN GMPs

Dear Sir:

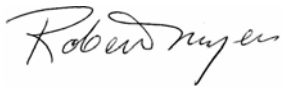
The Parenteral Drug Association (PDA) is pleased to provide these comments on the Proposal for Revisions to Canadian GMPs. PDA is an international professional association consisting of almost 10,000 individual members having an interest in the fields of pharmaceutical manufacturing and quality.

We link our comments to specific line items within the draft document. Our comments focus on the proposed increase in testing requirements upon import into Canada and the proposed location of retention samples within Canada. Each of the three changes identified in the accompanying table places an additional financial burden on the regulated industry that is not offset by an increase in the protection of the public health.

PDA would be pleased to meet with the HPFB to discuss our comments. Any questions regarding these comments should be addressed to Dr. Richard Levy, Senior Vice President, Scientific and Regulatory Affairs at levy@pda.org.

Thank you again for the opportunity to provide input.

Kind regards



Robert Myers
President, PDA

cc: Zena Kaufman, Chair, PDA Regulatory Affairs and Quality Committee
Richard Levy, Senior Vice President, Scientific and Regulatory Affairs, PDA