Before the
Department of Health and Human Services
Food and Drug Administration
Washington, D.C.

In Re: Petition to Provide Certification	)
to Congress Under Section 804(*l*) of	)
Chapter VIII of the Federal Food,	)
Drug and Cosmetics Act, and to	)
Authorize a Pilot Program for	)
Importation of Prescription Drugs	)
in the State of Illinois	)

AFFIDAVIT OF RANDALL L. STEPHANCHEW

Randall L. Stephanchew, being duly sworn, hereby deposes and states:

1. I am over the age of 18.

2. I am a citizen and resident of Canada and the Province of Manitoba.

3. I have personal knowledge of all the facts and opinions set forth in this Affidavit, and I would be competent to testify thereto if called upon to do so as a witness.

4. I am President of RLS Pharma Services, based in Winnipeg, specializing in full service pharmaceutical and regulatory affairs consulting for the health care industry. With extensive experience in pharmaceutical regulation, both in Canada and abroad, RLS Pharma Services is able to provide critical insight and guidance on how to interact with and understand the operations of Health Canada and how to meet their stringent pharmaceutical requirements. Full services include: setting up and administering Quality Assurance systems for Canadian companies and foreign companies locating in Canada; Good Manufacturing Practices (GMP) audits of foreign and Canadian facilities; GMP facility design; GMP consultation and customized training; writing Standard Operating Procedures (SOP's) and Quality Manuals; preparing and assisting with Drug Establishment License (DEL) applications; Good Clinical Practice (GCP) compliance audits, consultation and customized training; liaison with Health Canada and

interacting with Health Products and Food Branch (HPFB) Inspectors; and providing in-depth regulatory advice and assistance to clients.

5. My Curriculum Vitae is attached hereto indicating my professional qualifications.

6. I submit this Affidavit in support of the State of Illinois' Petition to Provide Certification to Congress Under Section 804(*l*) of Chapter VIII of the Federal Food, Drug and Cosmetics Act, and to Authorize a Pilot Program for Importation of Prescription Drugs in the State of Illinois. The conclusions contained herein, however, also apply generally to the subject of importation and reimportation of prescription drugs from Canada.

7. I submit this Affidavit on behalf of the State of Illinois, which has requested that I submit my opinion as an independent consulting expert. Prior to this consultation, I have not previously been retained by nor offered opinions on behalf of the State of Illinois.

8. In formulating the opinions contained in this Affidavit, I have previously been employed by Health Canada as a Drug Specialist and as Acting Operational Manager of the Health Products and Food Branch Inspectorate Office in Winnipeg. Health Canada is the agency in Canada similar to the United States Food and Drug Administration (FDA).

9. In the course of my official duties while with Health Canada, I have had frequent contact with the FDA and have participated on several inspections with their field inspectors while in Canada. In my opinion Health Canada and the FDA operate similarly and have a Memorandum of Understanding to work cooperatively, share regulatory information, and advise each other when they plan on entering each others' jurisdictions. Although they occasionally make different decisions on certain issues, they far more often decide matters in parallel.

10. In the course of my official duties while with Health Canada, I was one of eight Canadian Health Canada Inspectors selected to participate and evaluate the European

Community's Regulatory Authorities for Drug Good Manufacturing Practices, that resulted in the successful Mutual Recognition Agreement between Canada and the European Union. As such, Health Canada's drug regulatory system is considered to be one of the best in the world and further boasts one of the best drug safety records in the world.

11. In conjunction with my past function with Health Canada and as a licensed practicing Canadian Pharmacist, I am familiar with the Canadian pharmacy regulatory system and with safety issues related. I was also an expert advisor to senior Health Canada officials on the Internet Pharmacy/Canadian Mail Order Pharmacy file and was chosen to represent Health Canada at national and international meetings on this same topic.

12. As in the United States, prescription medications in Canada must be approved for sale. In the United States, the FDA must first approve the drug. In Canada, Health Canada must first approve the drug. The explicit elements surrounding this approval are defined and regulated through the Canadian Food and Drugs Act and Regulations. Fundamentally a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality.

13. Like FDA approval, Health Canada approvals of all drugs are manufacturer-specific and product specific, including such factors as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, appearance and labeling. To assure that drugs are safe, fulfill identity and strength specifications, and meet the quality and purity characteristics, all manufacturing must conform to current Good Manufacturing Practices (cGMP) standards. These drug standards in Canada are thus identical/equivalent to those in the United States.

14. Regulation of the distribution of prescription drugs in the United States is premised on a "closed system" meaning that from the manufacturer to the retailer (pharmacy),

including all points in the distribution chain, are regulated by the FDA. Similarly, the regulation of the distribution of prescription drugs in Canada is premised on a "closed system" of regulation by Health Canada of all points in the distribution chain.

15. In both the United States and Canada, once the drug reaches the pharmacy, regulation of its dispensing to patients becomes a matter essentially of state or provincial law as opposed to federal law. The "closed system," in both the United States and in Canada, requires nearly identical controls to verify where the drugs have been, the conditions under which they have been stored, and whether or not they might have been tampered with or contaminated.

16. In my opinion, the regulatory system in Canada is one of the most stringent in the world and is further supported by having one of the best safety records. Prescription medications that come from Canada are equally as safe as the prescription medications being dispensed in the United States.

17. Based on my own personal knowledge of the facts of this case and the drug regulatory schemes of the United States and Canada, Americans receiving drugs from Canadian Mail Order Pharmacies are receiving the same chemical substance and the same information under the same conditions as if they used a mail order pharmacy located in the United States.

FURTHER AFFIANT SAYETH NOT.

Randall L. Stephanchew

SUBSCRIBED AND SWORN TO BEFORE ME
this 7th day of April, 2004.

Notary Public