DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP - 7 2006

To Quality System Auditing Organizations:

The United States Food and Drug Administration (FDA) and the Therapeutic Products Directorate (TPD) of Health Canada (HC) presently have regulatory programs that use the services of third party quality system auditing organizations to perform inspections/audits of medical device manufacturers. In the interest of reducing the overall regulatory burden on device manufacturers, in accordance with the recently signed Security and Prosperity Partnership (SPP) agreement between Canada, Mexico, and the United States, Health Canada and the Food and Drug Administration are developing a **pilot** multi-purpose audit program (PMAP). The PMAP builds upon the information provided in a letter the FDA mailed to medical device manufacturers in November 2005 regarding third party inspections.

The purpose of the PMAP is to evaluate the effectiveness of performing a single third party inspection/audit of medical device manufacturers' quality systems that would meet the regulatory requirements of both countries.

The PMAP is intended to benefit its participants in a number of ways, including:

- for manufacturers, fewer distractions and interruptions in the work place
- for auditing organizations, the opportunity to better serve their clients by offering a wider range of services that would allow for the fulfillment of both US and Canadian regulatory requirements.

Although the inspections/audits would still encompass two separate but similar sets of requirements, we believe the downtime for a manufacturer will be minimized as a result of one auditing organization conducting the inspections/audits simultaneously.

If you are a qualified auditing organization under both the US FDA and HC programs, you are eligible to participate in this pilot to perform these multi-purpose audits.

More detailed information on the PMAP will be available soon on our websites. If you have questions regarding either the eligibility of the manufacturer or your own eligibility as an auditing organization, please contact either the US Food and Drug Administration or Health Canada as follows:

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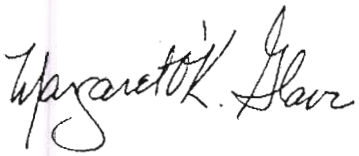
We encourage you to participate in this pilot program.



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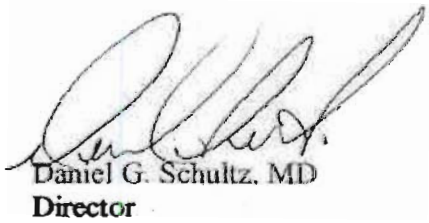

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