

Inspections, Compliance, Enforcement, and Criminal Investigations

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Department of Health and Human Services

Public Health Service
Food and Drug Administration
Rockville MD 20857

December 01 , 2009

Ms. Joyce Friesen
www.NovalisIntegra.com
160A Richmond Rd
Ottawa, ON K1Z6W2

Dear Ms. Friesen:

The Food and Drug Administration has completed an evaluation of your firm's corrective actions in response to our Warning Letter dated October 08, 2009. Based on our evaluation, it appears that you have addressed the violation(s) contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

/s/

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research