



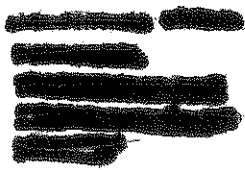
Health Products and Food Inspectorate  
Suite 1625, 1505 Barrington St.  
Halifax, Nova Scotia  
B3J 3Y6

Your file      Votre référence

Our file      Notre référence

JUN 08 2011

OF15-91-22-K0991\1



Dear Mr. Sharma;

**Re: Kutol Products Company Inc., 100 Partnership Way, Sharonville, OH, USA 45241**

The review of the information, received on May 3, 2011, as evidence of Good Manufacturing Practices (GMP) compliance for the aforementioned foreign site has been completed. The information provided demonstrates that the foreign site is in compliance with Division 2 of the *Food and Drug Regulations* (GMP) to fabricate, package/label and test over the counter pharmaceuticals (solutions), non sterile. Therefore, this foreign site may be listed on your Establishment Licence.

Please note that the assessment for this foreign site is valid until **DECEMBER 31, 2013**, unless new information is received or brought to our attention.

The Establishment Licence Unit is informed of this review.

Please note that you have the responsibility to insure that your foreign site continues to be GMP compliant and you are required to submit any new information that is brought to your attention.

Should you have any questions please do not hesitate to contact the undersigned. We thank you for your cooperation.

Sincerely,

Victoria Hurlbut  
Senior Compliance Officer  
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