DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 20 2014

Dr. S. Albert Edwards
16 Yorkshire Drive
Lincolnshire, IL 60069

Re: Docket No. FDA-2013-P-1509

Dear Dr. Edwards:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on November 4, 2013. Your petition requests the Agency meet with its Canadian Counterparts in the Health Protection Branch (HPB) to develop a Common Module 1 for the Electronic Common Technical Document / Regulated Product Submission (eCTD/RPS).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided under FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research