

Public Health Service



Food and Drug Administration Rockville MD 20857

December 2, 2013

FILE COPY

S. Albert Edwards, PharmD, RAC, FRAPS

Dear Dr. Edwards:

Your petition to the Food and Drug Administration requesting the Agency, via its representatives in the Office of Business Informatics, meet with their counterparts in Canada's HPB to craft a common module 1* for the eCTD/RPS, was received by this office on 11/4/2013. It was assigned docket number FDA-2013-P-1509/CP1, and it was filed on 12/2/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Director

Division of Dockets Management

FDA/Office of the Executive Secretariat (OES)