August 3, 2020

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061, HFA-305
Rockville, MD 20852

Dear Persons:

RE: Docket No. FDA-2013-P-1509:
A Common Module 1* for the US and Canada for the eCTD/RPS

The undersigned supplements this Petition with the following:

- Date of original Petition: October 27, 2013
- Date of receipt at Dockets Management Office: November 4, 2013
- Date of Petition's official filing: December 2, 2013
- Date of FDA's required 180 day response in accord with 21 CFR 10.30 (e) (2): March 20, 2014
- Date of FDA's Certified/Return Receipt Mailing [letter]: July 27, 2020
- Date of receipt by Petitioner: August 1, 2020

CURRENT ACTIONS REQUESTED:

A Common Module 1* for the US and Canada is still important to the overall success of the eCTD/RPS paradigm.

The Petitioner requests that FDA continue to pursue this and keep this Petition active.

The only modification to this Petition is to note that FDA and Canada now share a *common Electronic Submission Gateway*. The undersigned incorporates all other statements from the October 27, 2013 original Petition in this communication.

Sincerely,

(Dr.) S. Albert Edwards, PharmD, RAC, FRAPS

*The petitioner fully acknowledges the unique requirements of FDA's Office of Prescription Drug Promotion in CDER that could NOT be part of a Common Module 1.