October 27, 2013

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

2013 NOV -4 A 7:03

Dear Persons:

RE: A Common Module 1* for the US and Canada for the eCTD/RPS

The undersigned submits this petition under the Prescription Drug Amendments to the Federal Food, Drug, and Cosmetic Act; the Code of Federal Regulations, Title 21, Part 314 and/or any other statutory provision and any electronic submission guidance documents for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10 to request the Commissioner of Food and Drugs institute:

A Common Module 1* for the US and Canada: The FDA, 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.

This is the ACTIONS REQUESTED in this petition.

The STATEMENT OF GROUNDS for requesting the aforementioned actions are as follows:

1] Canada is already in discussions with CDER regarding the use of the electronic Gateway for the receipt and processing of electronic submissions.

2] US and Canadian submissions would be easier for the Office of Business Informatics staff to process if there was a Common Module 1*.

3] Based on the geographic proximity of the US and Canada, many regulated firms support applications in both countries. A Common Module 1* would facilitate/ease the filing burden [maintaining and using only 1 form rather than 2] for many regulated firms, including those outside the US and Canada.

ENVIRONMENTAL IMPACT: A categorical exclusion is requested under 21 CFR 25.34 for this petition.

*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.

[over]

FDA-2013-A-1509

2013-9699
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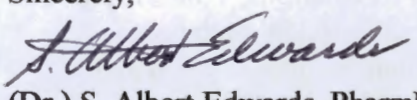
CERTIFICATION: The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

The petitioner does not own, operate, or have any business interest in any eCTD/RPS software or submission process.

The petitioner further requests a response from FDA, under 21 CFR 10.30 (e) (2) within the required 180 days. The petitioner is also aware of the Agency's workload and the Sequester; thus, the petitioner proposes an extension to 210 days for a response.

Sincerely,



(Dr.) S. Albert Edwards, PharmD, RAC, FRAPS
(b) (6)
[redacted]

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S. Albert Edwards, Pharm.D.
Drug Information Expert
(b) (6)
[redacted]

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