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September 30, 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

Dear Persons:

RE: Single Electronic Submission Gateway, ESG, Accounts, aka 'webtrader accounts' for Contract Research/Service Organizations, CRSOs, Submitting eCTDs for Sponsors

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, Parts 312 & 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:

1] The FDA's Office of Business Informatics staff has periodically communicated with Contract Research/Service Organizations informing them that they need **a separate webtrader gateway account for each Sponsor's submissions** and closed the CRSOs webtrader gateway account. Other CRSOs are continuing with their single webtrader gateway accounts. **Single webtrader accounts**, rather than multiple accounts-one for each Sponsor, **should be uniformly instituted for all CRSOs** by the Business Informatics staff.

This is the ACTION REQUESTED in this petition.

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

1] Closing single accounts is disruptive to CRSOs.

2] Creating multiple accounts, one for each Sponsor, that CRSOs must manage internally, with often small staffs, is an unnecessary business burden for CRSOs.

3] Multiple accounts can lead to wrong account selection. Wrong account selection will likely tie up the Business Informatics, BI, staff in error resolution; this is non-productive work. [over]

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4] Moving forward to 2016 and making the eCTD/RPS submission paradigm mandatory will place additional burdens on CRSOs and BI staff. Unless the Sequester is lifted, BI staffing is not likely to increase. Decreasing workload, i.e., streamlining the submission process, with single webtrader accounts for CRSOs is a necessary option based on increasing workload both for FDA and the regulated industry, including CRSOs.

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

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 a CRSO.

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,

S. Albert Edwards

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

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

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