



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

Re: Docket No. FDA-2013-P-1507

JUL 30 2019

Dear Dr. Edwards:

This letter responds to your citizen petition dated September 30, 2013, which was received by the Food and Drug Administration (FDA or the Agency) on October 17, 2013 (Petition). The Petition requests that FDA permit the uniform use of a single Electronic Submission Gateway account (WebTrader account) for each Contract Research Organization (CRO) rather than requiring that CROs maintain separate WebTrader accounts for each sponsor they represent.

The FDA Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The ESG provides a centralized, agency-wide communications point for securely receiving and processing electronic regulatory submissions. The primary method for low-volume submitters to make submissions through the ESG is through a WebTrader account. WebTrader is a simple, cost-effective web-based interface/portal used to send documents and receive receipts and acknowledgments from FDA.¹

At the time the Petition was submitted, FDA required a separate WebTrader account for each sponsor or applicant that a CRO represented. When initially implemented, the use of separate WebTrader accounts was standard practice in industry. However, since its implementation in 2006, the number of WebTrader accounts grew exponentially from 200 to over 15,000, a number that became unsustainable for both industry and FDA to manage. Consequently, in July 2016, after the Petition was submitted, FDA started permitting CROs to utilize a single WebTrader account.²

¹ For more information on the ESG and WebTrader accounts please see the FDA website at: <https://www.fda.gov/industry/electronic-submissions-gateway> and <https://www.fda.gov/industry/electronic-submissions-gateway/policiesguidance>.

² See <https://www.fda.gov/industry/create-esg-account/steps-cros-us-agents-and-consultants-obtain-esg-accounts>.

Docket No. FDA-2013-P-1507

FDA's allowance of single WebTrader accounts for CROs addresses the issues raised in the Petition. Accordingly, your Petition is dismissed as moot.

Sincerely,

A handwritten signature in dark ink, appearing to read "Dr. Janet M. Woodcock".

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research