

Contact: JASON ROCK
GlobalSubmit, Inc.
Phone: (215) 253-7474
Fax: (856) 504-0075

1880 John F. Kennedy
Boulevard, Suite 201
Philadelphia, PA 19103
www.globalsubmit.com



PRESS RELEASE

U.S. FDA Signals Intent to Reject eCTD's with Technical Issues

Anticipates Rejection of As Many As 5% of All Sequences

FOR IMMEDIATE RELEASE, Philadelphia, PA—February 2, 2009: eCTD adoption has accelerated across the industry over the past few years. As of January 1, 2008, the U.S. Food and Drug Administration (FDA) announced that the eCTD as the preferred format for electronic submissions. Submission quality is receiving increased focus and attention at the U.S. FDA in keeping with their mission to ensure drug safety and quality. Recently, FDA officials have expressed a commitment to increase their diligence and oversight with respect to submission quality and have signaled their intention to begin rejecting eCTD sequences having significant technical issues. Although no specific date has been established, it is anticipated that the Agency will announce their enforcement plans early in 2009.

Issues defined as 'significant' by Agency standards are those specifically highlighted within the current FDA guidance "*Specifications eCTD Validation Criteria*", dated March 10, 2008. FDA validation criteria defines the impact of a high severity error as "The error is a serious technical error which prevents the processing of the submission and will require resubmission. This recent move by the Agency has significant implications for all companies to ensure that submissions are prepared with increased due diligence to ensure quality prior to delivering dossiers to the Agency. This emphasis by the agency accentuates the importance of eCTD validation software to help ensure compliance and avoid technical rejections.

Reflecting on this trend, Jason Rock, GlobalSubmit CTO commented, "...this move by the Agency is a natural evolution of their overall strategy to protect public health and safety. Their commitment to improving their internal processes and technology is on-going and GlobalSubmit shares their vision to help organizations continuously improve the quality of eCTD submissions and accelerate new products to market faster."

Preceding their formal announcement, the U.S. FDA commented, "... our ultimate mission is to protect public health and safety. To this end, we are committed to improving the length of our review time as well as the quality of submissions to the mutual benefit of Sponsor organizations and the public at large. Our intent in pre-announcing our strategy is to ensure that all submissions are devoid of technical errors thus allowing our reviewers to focus their time evaluating the safety, effectiveness and quality of human therapeutics."

There are many issues and inefficiencies that result due to technical errors within eCTDs. As the number of eCTD sequences received by the FDA increases exponentially, it is unacceptable for the Agency to accept sequences that require manual correction prior to loading for internal reviewers. The FDA has been laying the groundwork for this action over the past few years. A formal announcement by the Agency will be forthcoming.

ABOUT GLOBALSUBMIT

GlobalSubmit is a products and services company that provides transparency in regulated healthcare products. The U.S. Food & Drug Administration and leading life sciences companies use our flagship applications, REVIEW™ and VALIDATE™, to review and validate electronic submissions. GlobalSubmit leads international efforts, comprising industry and government agencies, to standardize product and study information. The company is headquartered in Philadelphia, Pennsylvania.