

Authorized by Bridget Dooling, OMB via email on March 11, 2012

The prior approval for this collection had the following terms of clearance:

Per previous terms of clearance--and given that the burden estimates continue to swing dramatically from submission to submission--approval is granted for 2 years so that the estimates are more frequently updated. Where burden estimates swing dramatically, FDA should attempt to reassess estimates more frequently to ensure that the estimates on record are accurate. To the extent that the swings are actually due to poor estimation, FDA should attempt to improve the way estimates are produced.

FDA's response to the terms of clearance is as follows:

The estimates that FDA uses to request extensions for all of our ICRs are based on the number of submissions we receive over the previous few years (or records kept). A reason that the burden estimates for 0910-0435 "swing dramatically" is because of on-going Federal Court litigation and court "stays" on certain sections of 21 CFR part 203 and sections 205.3 and 205.50, resulting in fewer or no submissions for certain requirements. Portions of the PDMA regulations were stayed in connection with *RxUSA Wholesale, Inc., v. HHS*, 467 F. Supp.2d 285 (E.D.N.Y. 2006), aff'd, 2008 U.S. App. LEXIS 14661 (2d Cir. 2008)). In addition, the litigation itself had been administratively closed (with Plaintiffs' right to reopen) pending Congress' consideration of new legislation that, if enacted, would moot the issues raised by Plaintiffs. The understanding is that most if not all of this litigation has been settled, and thus should result in more stable submissions henceforth.