UNITED STATES FOOD & DRUG ADMINISTRATION

Adverse Event and Products Experience Reports;
Electronic Submissions
(FDA MedWatch)

OMB Control No. 0910-0645

**Request for Non-substantive, non-material change**:

I. Burden Adjustments:

Upon review of our ICR inventory, we find that provisions covered by OMB Control No. 0910-0672, established by rulemaking on September 29, 2010, became effective on March 28, 2011. The requirements are now incorporated into the applicable regulations at 21 CFR parts 312 and 320 (21 CFR 312 and 320). By non-substantive change request approved July 26, 2019, we consolidated provisions covered by 21 CFR 312 into OMB control no. 0910-0014 accordingly. Here, we are consolidating the provision to submit "*any serious adverse event, as defined in §312.32(a), observed during the conduct of the study as soon as possible but in no case later than 15 calendar days after becoming aware of its occurrence. Each report must be submitted on FDA Form 3500A or in an electronic format that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission*," as required under 21 CFR § 320.31(d) of our regulations, into OMB control no. 0910-0645. This information collection covers implementation of FDA's MedWatch safety reporting program, electronic submissions, including submissions using FDA Form 3500A. We believe that we have accounted for the attendant burden associated with such submissions in our most recent renewal of the information collection, however we did not include 21 CFR 320.31(d) among the referenced reporting requirements in our most recent supporting statement and seek to correct that here.

**Submitted: January 2020**