

UNITED STATES FOOD & DRUG ADMINISTRATION

Applications for FDA Approval to Market a New Drug

OMB Control No. 0910 0014

Request for Non-substantive, non-material change:

Upon review of our ICR inventory, we find that provisions covered by OMB Control No. 0910-0672, established by rulemaking on September 29, 2010 (75 FR 59935), became effective on March 28, 2011. The requirements are now incorporated into the applicable regulations at 21 CFR part 312 (21 CFR 312 – *Investigational New Drugs*), and we therefore intend to discontinue the collection 0910-0672. We invite OMB to review our supporting statement for 0910-0672 at Question 1, where we discuss our plans to consolidate the collections accordingly; as well as our supporting statement for 0910-0014 at Question 12, where we have included those provisions that were amended and account for the associated burden. We have, therefore, made no adjustment in burden to collection 0910-0014, but will discontinue OMB Control No. 0910-0672.

Submitted: July 2019