

UNITED STATES FOOD & DRUG ADMINISTRATION-

OMB Control No. 0910-0001 – Applications for FDA Approval to Market a New Drug

Request for Non-Substantive/Non-Material Change:

For efficiency of agency operations, we are requesting to include burden attributable to related activity under 21 CFR 200.5: *Mailing of important information about drugs*, currently approved under OMB control no. 0910-0754, into the instant information collection. There have been no changes to FDA's authority for, or the scope in, the information collection since its establishment in 2013, nor have we updated the associated procedural guidance issued in January 2014. At the same time, we have continually been reducing our estimate based on internal data and, upon our most recent review, we note only 4 submissions and 400 hours annually – a reduction by half of the currently approved burden – for this current evaluation period. We have added a new IC element to reflect this activity and intend on discontinuing OMB control no. 0910-0754 upon approval of our request.

Submitted: December 2025