

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:

As discussed in our supporting statement, the scope of the information collection is intended to cover all requirements found in section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) and implementing regulations in 21 CFR part 314. Upon OMB's informal recommendation, we are requesting to include burden attributable to regulations in 21 CFR part 315 pertaining to *Diagnostic radiopharmaceuticals*. Our *Diagnostic radiopharmaceuticals* regulations govern in vivo administration of radiopharmaceuticals and set forth factors relevant to their safety and effectiveness. Accordingly, we have added an information collection (IC) element to reflect an additional 6,750 hours and 4 responses of burden annually, for tasks associated with retaining and submitting to FDA required records. Upon OMB approval, we are requesting discontinuation of OMB control no. 0910-0409.

We are also requesting technical updates to our electronic **Form FDA 356h** to include Real World Evidence and Real-World Data (RWE/RWD) field values. Under the most recent reauthorization of the Prescription Drug User Fee Act (PDUFA VII) (as discussed in OMB control no. 0910-0297), FDA has committed to tracking and reporting on submissions containing real world evidence and real world data. Both Forms FDA 1571 and 356h are required to be submitted for all drug product applications. The new RWE/RWD fields will capture submissions with RWE/RWD based on the requirements set forth in the PDUFA VII commitment letter and the resulting Advancing Real World Evidence Program, so that FDA can track and report on its performance related to these commitments. In addition, collection of this data will support the consistent integration of real-world evidence data into the regulatory review and approval process for new drugs and biologics.

Submitted: July 2025