

UNITED STATES FOOD & DRUG ADMINISTRATION

Applications for FDA Approval to Market a New Drug

OMB Control No. 0910 0001

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. 0910-0786, established by rulemaking on October 6, 2016 (81 FR 69580) became effective on December 5, 2016. The requirements are now incorporated into the applicable regulations at 21 CFR part 314 (21 CFR 314). In our most recent renewal of OMB Control No. 0910-0001, however (please see agency burden table at pages 3-5, with accompanying notations at the bottom of page 5), we did not include the burden figures we attribute to these provisions. Rather, we explained that the burden was accounted for separately under 0910-0786. We are requesting this change to correct that error, and to ensure that all burden from the applicable regulations are reflected within the ICR that supports our drug application program. The resultant change is an additional 2,153 responses and an additional 2,789 burden hours to the collection, reflecting adjustment within the IC element entitled, “*Subpart B – Applications.*”

II. Changes to Form FDA 2252: *Transmittal of Annual Reports for Drugs and Biologics for Human Use*

We are also proposing minor changes to Form FDA 2252, draft attached. This form is available for electronic submission. We believe these revisions allow for a more streamlined approach for accepting data. These fields currently exist – the wording and layout will be slightly altered (changes have been italicized for clarification):

Field 7 – This will now be a drop-down field wherein the user can select the options of NDA, BLA, ANDA, and provide the associated Application Number. Users can ‘Add Row’ or ‘Remove Row.’ Previously, this field was an open text field.

Field 9 (g) – Renaming of the field from ‘STATUS REPORTS OF POSTMARKETING STUDY COMMITMENTS to STATUS REPORTS OF *OPEN* PMRS/PMCS (*leave blank if no open PMRs/PMCs to report*). This clarifies what is expected in this field.

Field 9 (h) – ‘STATUS OF OTHER POSTMARKETING STUDIES’ to ‘STATUS OF OTHER *OPEN* POSTMARKETING STUDIES’. The addition of the word ‘open’ further clarifies what is expected in the field.

As a result of these changes we have made no adjustment to the cumulative burden for submission.

Submitted: July 2019