UNITED STATES FOOD & DRUG ADMINISTRATION

OMB Control No. 0910-0230

Adverse Drug Experience Reporting; Combination Products –
21 CFR part 314 and 21 CFR part 4

Request for Non-Substantive/Non-Material Change:

For operational efficiency, we are requesting to add burden attributable to provisions set forth in 21 CFR part 4 subpart B, currently approved in OMB control no. 0910-0834, into the information collection. Established through agency rulemaking that became effective in 2021 (RIN 0910-AF82; 81 FR 92603), specific provisions include 21 CFR 4.103, which provides that when information regarding an event that involves a death or serious injury, or an adverse event, associated with the use of a combination product is received by the product sponsor, the information must be provided to the other constituent part applicant(s) no later than 5 calendar days after receipt. Relatedly, 21 CFR 4.104 explains how and where to submit reports. Finally, 21 CFR 4.105 provides for associated recordkeeping. We have added the IC "*Postmarketing Safety Reporting for Combination Products*," to reflect 198 responses and 89 hours annually to account for the estimated burden. These requirements are described in 21 CFR § 314.80(a), as well as regulations in 21 CFR § 600.80(a) and 21 CFR § 803.3, where we are submitting corresponding requests to modify control nos. 0910-0308 and 0910-0437 with regard to these notifications as they pertain to biologic-led or device-led combination products. Burden we attribute to the provisions of 21 CFR part 4 subpart A setting forth current good manufacturing practice requirements is discussed and accounted for in control no. 0910-0523. Upon OMB approval of our request to account for the postmarket safety reporting for combination products in the respective collections, we intend to discontinue control no. 0910-0834, established for the rulemaking noted above.

Submitted: March 2023