

UNITED STATES FOOD & DRUG ADMINISTRATION

OMB Control No. 0910-0308

Biological Product Postmarket Adverse Experience Reporting; Combination Products –
21 CFR part 600 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 the 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 element “*Postmarketing Safety Reporting for Combination Products*,” to reflect 198 responses and 89 hours annually to account for the estimated burden associated with requirements in 21 CFR part 4 subpart B. Requirements are described in 21 CFR 600.80(a), as well as regulations in 21 CFR § 314.80(a) and § 803.3, where we are submitting corresponding requests to modify control nos. 0910-0230 and 0910-0437 with regard to these provisions as they pertain to drug-led or device-led combination products. Burden we attribute to the provisions in 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