

UNITED STATES FOOD & DRUG ADMINISTRATION

Data to Support Drug Product Communications
OMB Control No. 0910-0695

Request for Non-substantive Change to Approved Generic Clearance:

Upon review and preparation for our request to renew the information collection, we have become aware of language in our supporting statement that communicates “*in some cases, FDA sponsorship will not be made known to respondents prior to data collection out of concern for the potential introduction of bias to study results. In such cases, FDA sponsorship will be made known after the data are collected.*” While we are unaware of any collection activity implemented under this generic clearance in which FDA’s sponsorship was not disclosed, we do not intend for this language to be included in the supporting statement. We are requesting to clarify that FDA sponsorship for proposed information collection will be shared with intended respondents, as required by the PRA, and that any future requests for information collection under the approved generic will address this disclosure element specifically until renewal/extension of the information collection is approved by OMB. FDA will prepare a 60-day notice for publication in the Federal Register to invite public comment on the information collection. In the interim, we have revised our supporting statement, part A, to remove the language from Question 10.

Submitted: July 2022