UNITED STATES FOOD & DRUG ADMINISTRATION

Investigational New Drug Applications

OMB Control No. 0910-0014

Request for Non-substantive, non-material change:

We are requesting to include the guidance document entitled, "*Pharmacogenomic Data Submissions*," currently approved under OMB control number 0910-0557, into the information collection associated with investigational new drug applications and associated regulations in 21 CFR part 312. Specifically, sponsors submitting or holding INDs, NDAs, or BLAs are subject to FDA requirements for submitting relevant data regarding drug safety and effectiveness (including 21 CFR 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12). Because the regulations were developed before the advent of widespread animal or human genetic or gene expression testing, they do not specifically address when such data must be submitted. The guidance document provides recommendations to sponsors holding investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) on:

(1) when to submit pharmacogenomic data to the Agency during the drug or biological drug product development and review processes,
(2) what format and content to provide for submissions, and
(3) how and when the data will be used in regulatory decision making.

We ultimately plan to revise the guidance consistent with our proposed *Guidance Agenda 2020*, as posted on our website at https://www.fda.gov/media/134778/download. At the same time, we have not received any pharmacogenomic submissions since 2013 although we seek to retain the collection for such a submission. Accordingly, we are requesting to consolidate any burden with related submission elements under control number 0910-0014. At this time, we believe no adjustment in burden is necessary.

June 2020