

UNITED STATES FOOD & DRUG ADMINISTRATION

OMB Control No. 0910-0120: Premarket Notification Submissions (510(k)); 21 CFR Subpart E  
OMB Control No. 0910-0850: Use of Public Human Genetic Variant Databases to Support  
Clinical Validity for Genetic and Genomic-Based in Vitro Diagnostics

**Request for Non-Substantive/Non-Material Change:**

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and implementing regulations in 21 CFR part 807 subpart E (§§ 807.81 through 807.100) establish premarket notification procedures. As communicated in our supporting statement, the information collection includes the recognition of standards as part of the premarket review process. At <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/standards-and-conformity-assessment-program> we communicate how consensus standards can be used in premarket submissions. As discussed more specifically at <https://www.fda.gov/medical-devices/precision-medicine/fda-recognition-public-human-genetic-variant-databases#resources> and in the guidance document entitled, “*Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics*,” (April 2018), use of the information helps ensure patients receive accurate, reliable, and clinically meaningful test results, while promoting innovation in test development. The guidance document explains that a “genetic variant database” is a publicly accessible database of human genetic variants that aggregates and curates reports of human genotype-phenotype relationships to a disease or condition with publicly available documentation of evidence supporting those linkages. The guidance document also describes how publicly accessible databases of human genetic variants can serve as sources of valid scientific evidence to support the clinical validity of genotype-phenotype relationships in FDA’s regulatory review of both NGS (next generation sequencing)-based tests and genetic and genomic tests based on other technologies. Finally, the guidance document describes a process for database administrators to apply for FDA recognition of certain databases for use in premarket submissions.

We attribute burden for the application for recognition of a genetic database, and burden attendant to maintenance and public disclosure of policies, procedures, and conflicts of interest as discussed in the guidance document. Although we intend to discontinue control no. 0910-0850 upon OMB approval however, we believe the previously estimated 5 responses and 505 hours annually for activities discussed in guidance is already accounted for in our estimate for premarket submission activities cumulatively. We have therefore made no adjustment to the currently approved burden estimate in control no. 0910-0120.

**Submitted: August 2023**