UNITED STATES FOOD & DRUG ADMINISTRATION-

OMB Control No. 0910-0014 – Investigational New Drug Requirements

Request for Non-Substantive/Non-Material Change:

This information collection supports implementation of section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) and of the licensing provisions of the Public Health Service Act (42 U.S.C. 201 et seq.) that govern investigational new drugs and investigational new drug applications (INDs). Implementing regulations are found in part 312 (21 CFR part 312), and provide for the issuance of guidance documents (see § 312.145 (21 CFR 312.145)) to assist persons in complying with the applicable requirements. The information collection applies to all clinical investigations subject to section 505 of the FD&C Act.

For efficiency of agency operations, we are requesting to include burden we attribute to related activity, currently approved in OMB control no. 0910-0893, into this collection. Specifically, 21 CFR part 300.200 requires the submission of an annual report by sponsors and manufacturers who provide an "*eligible investigational drug*" under the Right to Try Act. The regulation also establishes content and format elements and requires that information be submitted to FDA no later than March 31 of each year, including data for the preceding calendar year. Respondents use **Form FDA 5023** entitled "*Right to Try Reporting Requirement: Annual Summary*," currently available for download from our website at https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try-annual-reporting-summary. As required by the applicable statute, section 561B of the FD&C Act (21 U.S.C. 360bbb-0a), the information is submitted to an FDA-designated point of contact, and in accordance with instructions to be posted at: https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try. We have added the IC element, "*Right to try reporting requirements*," and have added 10 responses and 3 hours annually to reflect the burden we attribute to required activities.

Submitted: December 2025