

UNITED STATES FOOD & DRUG ADMINISTRATION

OMB Control No. 0910-0014

Investigational New Drugs – 21 CFR part 312

Request for Non-Substantive/Non-Material Change:

For operational efficiency, we are requesting to add burden that may be attributable to activities discussed in the procedural guidance document entitled, “*Special Protocol Assessment*” (issued originally May 2002, revised April 2018), currently approved in control no. 0910-0470, into the information collection. FDA issues guidance documents consistent with 21 CFR 312.145 to help respondents comply with certain requirements. The guidance document provides information on associated procedures and general policies adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). Sponsors may ask to meet with FDA to reach agreement on the design and size of certain clinical trials, clinical studies, or animal studies to determine if they adequately address scientific and regulatory requirements for a study that could support marketing approval. Included in the guidance is instruction on format and content of requests. As discussed in the guidance, respondents submit requests to meet with FDA in conjunction with information submitted using Form FDA 1571, currently approved for use as part of the information collection. Accordingly we have adjusted the IC element, “*CDER: 312 Subpart B – IND Application, including content and form, safety reports, and annual reports,*” to reflect an additional 305 responses and 3,250 hours annually. Upon OMB approval, we intend to discontinue control no. 0910-0470.

Submitted: March 2023