

UNITED STATES FOOD & DRUG ADMINISTRATION

OMB Control No. 0910-0332

Humanitarian Use Devices – 21 CFR 814 Subpart H

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

Section 402(j)(5)(B) (42 U.S.C. 282(j)) of the Public Health Service Act (PHS Act), requires a certification to accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 354, 360e, or 360j(m)), or under section 351 of the PHS Act (21 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification that all applicable requirements of section 402(j) of the PHS Act have been met. The certification is effected by respondents' completion of **Form FDA 3674** entitled, "*Certification of Compliance – Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank.*" Relevant regulations are found in 21 CFR parts 312 (investigational new drugs), 314 (applications to market new drug), 601 (biologic license applications), 807 (premarket device notifications), and 814, subpart H (humanitarian use devices – HUDs) and discussed in FDA's notice of implementation of the certification on December 12, 2007 (72 FR 70599). For operational efficiency, we are seeking to include burden associated with certifications for HUD submissions by adding 3 hours and 4 responses annually to the currently approved estimate. We believe that we have otherwise accounted for the cumulative burden associated with the certifications by distributing the element among the approved information collections supporting the respective application types. Upon OMB approval of this request, we intend to discontinue OMB control no. 0910-0616.

**Submitted: March 2023**