

UNITED STATES FOOD & DRUG ADMINISTRATION

Establishment Registration and Device Listing for
Manufacturers and Initial Importers of Devices

21 CFR Part 807

OMB Control Nos. 0910-0625 and 0910-0852

Request for Non-substantive Change and Request to Discontinue:

Agency regulations in 21 CFR part 807 require that anyone engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use register with and submit listing information to the FDA. Provisions in part 807 are currently approved under OMB control no. 0910-0625. Included among the requirements are content and format criteria for specific notifications, as set forth in Subpart E: Premarket Notification Procedures.

The draft guidance document entitled, “*Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers*” (December 2014), was developed to assist respondents with regard to notifying FDA of the transfer of a 510(k) clearance from one person to another, and explains procedures FDA and industry should use to ensure public information in FDA’s databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date. Although submission of information regarding the transfer of a 510(k) clearance is not necessarily required under the regulations, we regularly receive such notifications from respondents. While we ultimately plan to finalize the guidance, it continues to remain useful to respondents. The information collection recommendations found in the draft guidance are currently approved under OMB control no. 0910-0852.

We are requesting to consolidate burden attributable to the recommendations found in the draft guidance with the related information collection provisions found in 21 CFR part 807. Accordingly, we have added an additional **6,113** responses and **9,152** hours annually to 0910-0625. Upon approval of this request, we intend to discontinue the collection of information currently approved under 0910-0852.

Submitted: May 2021