UNITED STATES FOOD & DRUG ADMINISTRATION

Product Jurisdiction and Combination Products

OMB Control No. 0910-0523

Request for non-substantive/non-material change:

This information collection supports section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353(g)), and implementing regulations in 21 CFR part 3. We established the information collection, in part, to, "*enhance the efficiency of agency management and operations by providing procedures for determining which agency component will have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute,"* (see 21 CFR part 3.1). Since doing so, more recent legislation and agency processes have effected submissions relating to combination product jurisdiction and we are currently proposing to make corresponding changes to the information collection. Specifically, we are soon publishing a 30-day notice in the Federal Register to discuss changes to section 503(g) as amended by the 21st Century Cures Act (P.L. 114-255) ("Cures Act"); changes discussed in our proposed rule of May 15, 2018 (RIN 0910-AH71; 83 FR 22428), and, finally, changes resulting from recommendations found in relevant agency guidance documents. Among those is the guidance document entitled, "*How to Prepare a Pre-Request for Designation (Pre-RFD),"* currently approved under OMB control no. 0910-0845. For efficiency of agency operations, we are discontinuing the collection of information associated with control no. 0910-0845 and are proposing to consolidate it here with similar collection activity. This results in an adjustment of 136 additional responses and 1,768 additional hours annually.

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