UNITED STATES FOOD & DRUG ADMINISTRATION

Prescription Drug User Fees

OMB Control No. 0910-0297

No Material or Non-Substantive Change to a Currently Approved Collection (83C):

This change request supports the Food and Drug Administration (FDA, us or we) Prescription Drug User Fee program. Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), we have the authority to assess and collect user fees for certain new drug applications (NDAs) and new biologics license applications (BLAs). Relatedly, sections 735 and 736 also provide for waiver, reduction, refund, and reconsideration requests. Accordingly, we established the information collection currently approved under OMB control no. 0910-0693 entitled, "*Guidance for Industry –User Fee Waivers, Reductions, and Refunds for Drug and Biological Products*," noting that the approval also includes Form FDA 3971 (*Small Business Waivers and Refund Requests*). For efficiency of agency operations, we are seeking OMB approval to consolidate information collection pertaining to the submission of the prescription drug user fee cover sheet with burden we attribute to related waiver, reduction, refund, and reconsideration requests, both as governed by sections 735 and 736 of the FD&C Act. This change request includes the referenced guidance (issued September 2011; revised January 2015 and August 2018 to reflect revision of the OMB expiration date), and associated Form FDA 3971. Also, we have retitled the collection simply "Prescription Drug User Fees" and have made a corresponding adjustment to the estimated burden to reflect burden previously accounted for under OMB control no. 0910-0693. This results in an increase of 2,630 hours and 183 responses.

Submitted: August 2020