FOOD AND DRUG ADMINISTRATION
Non-Substantive Change Request

OMB Control Nos. 0910-0727; 0910-0297; 0910-0718; and 0910-0511.

Date: August 8, 2017

Purpose:

The Food and Drug Administration (FDA) is requesting non-substantive changes to some of its user fee cover sheets. Specifically, the changes are listed below, corresponding to the respective OMB Control Numbers:

Program; OMB Control No.	**Currently**	**Proposed**
GDUFA; 0910-0727	ANDA Fee	No change
	PAS Fee	Removed PAS from entire form (no more fees for PAS))
	Facility Fee	Added Contract Manufacturing Organization (CMO) fee
	DMF Fee	No change
		Added Program fee tiers
		1-5 approved ANDAs - Small
		6-19 approved ANDAs - Medium
		20 or more approved ANDAs - Large
	Positron Emission Tomography (PET)	No change
		Added No ANDA fee for drugs manufactured by State or Federal entities not intended for commercial
	Instructions for completing the form	Made changes related to items noted above, and other clarifying instructions
	Currently	**Proposed**
PDUFA; 0910-0297	Original Applications	No change
	Supplements	Removed supplements from entire form (no more fees for supplements)
	Priority Review Voucher (was previously only Tropical Disease Voucher)	Added the ability to enter new type of priority review voucher (Medical Counter Measure) and voucher number in addition to Tropical Disease Voucher
	Instructions for completing the form	Made changes related to items noted above, and other clarifying instructions

	Currently	Proposed
BsUFA; 0910-0718	Initial/Reactivation	Edited question regarding previously paid BPD fees
	351(k) Application	No change
	Supplement	Removed supplements from entire form (no more fees for supplements)
	Small Business question	Moved the location of this question
	Instructions for completing the form	Made changes related to items noted above, and other clarifying instructions
	Currently	**Proposed**
MDUFA; 0910-0511		Adding a checkbox for De Novo submissions

Background:

On August 3rd, Congress enacted the Food and Drug Administration User Fee Reauthorization Act of 2017 (FDARA). The legislation reauthorizes the various user fees that help fund the agency's review and oversight of prescription drugs, generic drugs, medical devices, and biosimilars. FDA's Office of Financial Management (OFM) is responsible for the administration of the user fee programs by maintaining an accounts receivable system for user fee invoicing, collections, reporting, and data maintenance. To facilitate respondent transactions with the agency, cover sheets are used to submit necessary information to FDA. The cover sheet gathers the minimum amount of information necessary to determine whether a fee is required, to determine the amount of the fee, and to allow FDA to track payments. Respondents may use electronic means to create the cover sheets, however paper submissions may also be submitted as appropriate.

Accordingly, FDA is requesting approval to its user fee cover sheets as necessitated by the passage of FDARA and as indicated in the table above.