NON-SUBSTANTIVE CHANGE

0910-0498

FDA is requesting a non-substantive change to 0910-0498 to add CDER back into this ICR. CDER originally opted out of the recent renewal but now wants to be included as their new database is not available as yet to go forth with their own ICR. The form CDER will use was part of the previous submission for extension of OMB approval. It has not been changed for CDER use. This form will be used by CDER only and is indicated as such on the attached form. The form in this submission is a mock-up of the form while it is being revised by PSC. The final version of the form will have the OMB No. 0910-0498, the public protection provision, and the new expiration date of 03/31/2018. The form number will be FDA 3613f.

Included in this non-substantive change is the burden cost. At an average of $132 (for original requests and duplicates the burden cost is estimated to be $695,758. In addition, the hourly burden added to 0910-0498 as a result of CDER being folded back into this ICR is:

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Drug Evaluation and Research	5,251	1	5,251	2	10,502