

Application for Food and Drug Administration Approval to Market a New Drug

OMB Control Number 0910-0001

CHANGE REQUEST (83-C)

Date: February 24, 2015

Now that the January 16, 2009 (74 FR 2849) final rule has been fully implemented, we are already capturing the data in the “Total Annual Responses” column when we update these estimates from CDER’s Document Archiving, Reporting & Regulatory Tracking System for 21 CFR 314 (0910-0001), (§§ 314.94(a)(7)(i), 314.96(a)(1), and 314.97), and it would be duplicative to also maintain the same data under 0910-0630.

Table 1-- Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
314.94(a)(7)	84	1	84	72	6,048
314.96(a)(1)	1	1	1	72	72
314.97	1	1	1	72	72
TOTAL					6,192