0910-0595
Non-Substantive Change
Authorized by Bridget Dooling, OMB via email on September 7, 2010

FDA is requesting to amend this ICR to increase the number of respondents (State and Local Public Health Officials; Unapproved EUA (Emergency Use Authorization)) product. FDA would like to amend the ICR to increase by 80 the number of respondents who administered an unapproved product and are required to report to FDA under the conditions of an authorization issued during the H1N1 influenza pandemic. The increase of 80 respondents is due to an unforeseen number of respondents administering the drug for H1N1.

The total number of State and Local Public Health Officials (currently approved at 30) plus 80, totals 110 respondents.

The increase is as follows:

80 respondents multiplied by 4 reports per year = 320 annual responses.

320 responses multiplied by 5 hours (2 hrs for reporting; 3 hrs for recordkeeping) = 1,600 hours increase in burden.

NOTE: The frequency of reporting (4 times per year) is not changing with this non-substantive change request. The hours for reporting (2 hrs) and recordkeeping (3 hrs) also is not changing.