

07/27//2011

To: Fumie Griego

OMB Desk Officer

From : Denver Presley

FDA / PRA Staff

RE: Justification Memo for No material Non substantive Change

To The Currently Approved Information Collection for 0910-0682

Fumie:

Based on the July 27,2011 conference call with CFSAN personnel and as per your request , I am submitting a clean version of all the revised documentation.

Thanxs