Export Certificates for FDA Regulated Products Under U.S.C. Sections 801(e) and 802

(OMB Control Number 0910-0498)

CHANGE REQUEST (83-C)

Date: June 25, 2015

FDA is requesting a non-substantive change to 0910-0498 to add Form FDA 3613f for use by persons who export certain FDA-regulated products and request that FDA certify that their products meet certain requirements under section 801(e)(4) of the FD&C Act. This form will be used by CDER only and is indicated as such on the attached form. On June 15, 2015, OMB issued a Notice of Action approving this action (ICR Reference Number 201506-0910-016) and we are now submitting Form FDA 3613f to be added to 0910-0498 for CDER-regulated products.