"FDA Approval to Market a New Drug"
(OMB Control Number 0910-0001)

Change Request (83-I)

January 19, 2016

We would like to remove the signature block from the FDA Form 3331a in order to make it simpler for industry to submit their form to us. The FAR regulation 21 CFR 314.81 does not require a signature and the form FDA Form 3331 is not part of the regulation. Currently the instructions on the FDA Form 3331a instruct industry to print, sign, scan and submit the form to us. We believe it would save industry time if they were allowed to submit without having to print, scan and manually sign the form. When considering digital signatures, Adobe reader does not allow a digital signature and so we do not want to mandate digital signature for those firms who may only have the free adobe reader and not the full paid complement of adobe on their desktop. We are aware that FDA Form 3911 is another example of a CDER form that will not require a signature. Another example of a form with no signature, which CDER accepts to receive biological deviation reports, is the CBER Biological Product Deviation Report (BPDR) form 3486.

We would also like to request the change of the FDA Form 3331a form name from "NDA-Field Alert Report" to "NDA & ANDA Field Alert Report" to do away with any confusion about which applications are required to submit a Field Alert Report (FAR). This name change was originally suggested by the forms working group and agreed to by the XML FAR project working group.