0910-0498
83-C Non-substantive change

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request in order to add an electronic option for submitting requests for export certificates. This effort satisfies, with regard to human drugs, the terms of clearance for OMB #0910-0498, exp 3/31/2018, which states: "FDA shall make this collection electronically submittable as soon as possible to be in compliance with the [GPEA]." This will allow respondents the option of submitting requests for export certificates via the CDER Export Certification Application and Tracking System (CDEReCATS) module of the FDA Unified Registration and Listing System (FURLS). Respondents are required to register and list in FURLS (see OMB #0910-0625), and therefore already have all the software and training necessary to use the system. There is no change to the information requested or data elements; we are simply making available the option to submit the same information via electronic means. Though we expect the majority of respondents to make use of the electronic submission option, respondents can still submit the information using the paper forms (FDA 3613f). We do not expect a change in the hour or cost burden estimates.