

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

**0910-0498**

**JUSTIFICATION MEMORANDUM FOR 83-C CHANGE REQUEST**

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) in order to add an electronic option for submitting requests for export certificates. This effort satisfies, with regard to cosmetics, the terms of clearance from the NOA dated May 29, 2009, for OMB #0910-0498, exp. 3/31/15, which states: “FDA shall make this collection electronically submittable as soon as possible to be in compliance with the Government Paperwork Elimination Act.” This will allow respondents the option of submitting requests for export certificates via the Certificate Application Process, which is part of FDA Unified Registration and Listing System (FURLS). The option for electronic submissions will reduce the time and cost for respondents and facilitate the review of their requests. 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 may still submit the information using the paper form (FDA 3613d).

We do not expect a change in the hour or cost burden estimates because, currently, respondents must obtain the same information to prepare their request, and, on average, we expect them to take the same amount of time to submit it whether they prepare that information on a fillable pdf and press “print” or on an electronic submission system and hit “submit.” Therefore, as a conservative estimate for purposes of this submission, we do not estimate a change in the hour or cost burden estimates. In the future, when respondents have become familiar with the new electronic submission system and its advantages, they may find that their submissions take less time. We can better assess that reduction in hour burden once the new system is up and running.