

UNITED STATES FOOD & DRUG ADMINISTRATION

Export Certificates for FDA Regulated Products
OMB Control No. 0910-0498

Non-Material/Non-Substantive Modification to a Currently Approved Collection (83-C):

To implement statutory provisions added December 29, 2022, by section 3304 of the Consolidated Appropriations Act, we are updating **Form FDA 3613g** entitled, “*Certificate for Device Not Exported from the United States Requests.*” Amended section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act modifies the FDA’s authority to issue certain certificates. FDA will no longer review requests for Certificates for Devices Not Exported from the United States (CDNE) under former section 801(e)(4)(E)(iii) of the FD&C Act received on or after December 29, 2022. As a result of the new provisions, we are modifying the form as follows:

- removal of references to the content of section 801(e)(4)(E)(iii), as this provision was repealed;
- modifications consistent with the amended statute; and
- conforming edits to the instructions, referenced page numbers, formatting, etc.

We have included a pdf version of the form denoting the proposed changes, however we estimate no change in burden associated with completing and submitting Form FDA 3613g and have therefore made no adjustments.

Submitted: March 2023