

United States Food and Drug Administration

Export Certificates for FDA Regulated Products
Federal Food, Drug, and Cosmetic Act Sections 801(e) and 802

OMB Control No. 0910-0498

No Material or Non-Substantive Change to a Currently Approved Collection (83-C)

FDA is requesting approval of a non-substantive change to form FDA 3613g, "Certificate for Device Not Exported from the United States Requests," associated with OMB Control No. 0910-0498. This submission includes the new version of the form. We are correcting the form by removing the Privacy Act statement.

OMB Control No. 0910-0498 "Export Certificates for FDA Regulated Products Federal Food, Drug, and Cosmetic Act Sections 801(e) and 802" supports Food and Drug Administration (FDA) implementation of sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 801(e)(4) of the FD&C Act provides that persons exporting FDA-regulated products may request FDA to certify that the product meets the requirements of sections 801(e) or 802 or other requirements of the FD&C Act.

It has come to our attention, and we have confirmed with the FDA Privacy Office, that it is not appropriate to include a Privacy Act statement on the form FDA 3613g because the *CDRH Export Certification Application and Tracking System*, through which the form is submitted, is covered by the FDA Unified Registration and Listing System (FURLS) Privacy Impact Analysis (PIA). This system is not a Privacy Act system, so there is no need for a Privacy Notice. Please note the Privacy Office review included both CDRH and CBER components of the form. The recommendation to remove the Privacy Act Statement applies to the entire form.

We have therefore corrected the form by removing the Privacy Act statement below, which was included in error and is not relevant to the form:

"PRIVACY ACT STATEMENT

Authority: The information collected in this form is provided to comply with the Privacy Act of 1974 (P.L. 93-579) for individuals seeking non-employee student, post-graduate or senior scientist training opportunities from the Food and Drug Administration. Purpose and Uses: All information collected in this form is required to begin the Traineeship. Completed forms are used by the Staff to meet program selection and on-boarding requirements. Information is also shared with the FDA personnel authorized to administer the program. Effects of nondisclosure: Disclosure of the information is voluntary; however, collection of this information is necessary to continue with the FDA."

September 2022