United States Food and Drug Administration

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

OMB Control No. 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 animal food, animal drugs, and veterinary devices, the terms of clearance from the NOA dated May 29, 2009, for OMB #0910-0498, expiration date 04/30/2021, 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 CVM Export Certification Application and Tracking System (CVMeCATS) 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. Minor changes were made in converting the existing paper forms to electronic. The electronic system will not request the following information currently requested on the existing paper forms:

- Paper Form FDA 3613, sections 5A., 5B., and 5C: information about recall, injunction, and seizure. The electronic system will obtain this information from the FEI number.
- Paper Form FDA 3613, section 8 and Paper Form FDA 3613a section 6: yes or no question about listing the destination country on the certificate. This question is unnecessary since CVM requires all certificates issued have the importing country written on them.
- Paper Form FDA 3613 and 3613a, section 1C: Shipping Account Number. These certificates will be delivered electronically.
- Paper Form FDA 3613 and 3613a, section 2: no longer requires both the Firm name and FEI number. Respondents may enter one or the other.
- Paper Form FDA 3613a: information about Section 802 of the Act. This information does not apply to animal products.
- Paper Form FDA 3613a: information about Product Class. This information does not apply to animal products.
- Paper Form FDA 3613b, section 2B.1 – 2B.3: information regarding unapproved biological drugs. This information is not relevant to CVM and thus no longer necessary.

- Paper Form FDA 3613b: information about the facilities involved in manufacturing of the exported product. The license number and the Firm FDA Registration number is no longer needed; only the FEI number is needed.
- Paper Form FDA 3613b: information about shipping account. We will no longer ask for the mail carrier name or account number. We will only ask for the shipping label.

The electronic system will ask respondents to identify their product with the use of a code, as is currently done on the similar electronic Form FDA 3613 forms for CDER and CDRH products. An animal drug product will be identified by its National Drug Code (NDC). Form FDA 3613a will ask respondents to upload labels of each product listed on the application to conform with the Center's other two forms (3613 and 3613b) and as is standard operating procedure for CDER and CDRH. Form FDA 3613b will ask to include the telephone and fax number of the billing contact if different from the requestor. This is in case an email address is entered incorrectly. In order to conform with CDER and the World Health Organization we will include a Remarks section for Form FDA 3613b.

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 (Forms FDA 3613, 3613a, and 3613b). We do not expect a change in the hour or cost burden estimates.

We would like to obtain OMB approval of the electronically submitted version of Forms FDA 3613, 3613a, and 3613b, so that IT development work may continue in accordance with the contracting timeline.

Submitted: March 2020