

UNITED STATES FOOD & DRUG ADMINISTRATION

Imports and Electronic Import Entries

OMB Control No. 0910-0046

Request for non-substantive/non-material change:

This information collection supports FDA regulations in 21 CFR part 1, subparts D and E, which pertain to imported products regulated by the Food and Drug Administration. Currently, and consistent with 21 CFR 1.95, respondents use Form FDA 766 entitled “*Application for Authorization to Relabel or to Perform Other Action of the Federal Food, Drug, and Cosmetic Act and Other Related Acts*” to provide necessary information for relabeling or performing “*other action to bring [an] article into compliance with the Federal Food, Drug, and Cosmetic Act*” The form is available on the internet at <https://www.fda.gov/industry/actions-enforcement/reconditioning>, and may be submitted as a paper-based form, by email, or through our Import Trade Auxiliary Communication System (ITACS). We have made changes to Form FDA 766, as enumerated below, to better align with our operational systems and based on informal user experience, and we believe these changes will enhance processing of the necessary information.

1. The form name changed to “Request For Authorization To Relabel or Recondition Non-Compliant Articles”.
2. Added Section Numbers 1-5 for each section of the form. Moved Section headers to left justified instead of centered.
3. Added Field Numbers for each field on the form
4. Changed the “Date” field to “Application Date”
5. Removed Sample Number and Carrier fields
6. Added “Line No.” to “Entry No.” field
7. Split out “Amount and Marks” field into “Quantity”, “Quantity to be Reconditioned” and “Production Codes” fields
8. Changed the word “merchandise” to “article(s)” throughout the form
9. Added “FDA” to “Action on Application” Section name
10. Changed “Place” field to “Location where reconditioning operation occurred”
11. Added field 20b. Contact Information
12. Changed “Typed Name of Applicant” field to “Applicant and Firm Name”

13. Changed “Signature” field to “Applicant’s Signature”
14. Changed “Data on Cleaned Goods” Section name to “Data on Reconditioned Article(s)”
15. Changed “Good Portion” field to “Acceptable Portion”
16. Changed “Did importer clean entire shipment?” field to “Did importer recondition entire shipment?”
17. Added “Name” to “Inspecting Officer” field
18. Removed Director of District Section
19. Added instructions on pages 3 and 4 for completing each field on the form.

We therefore request OMB approval for these changes.

November 2020