APPLICATION FOR AUTHORIZATION TO RELABEL OR RECONDITION NON-COMPLIANT ARTICLES

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Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please do NOT send your completed form to the above PRA Staff email address.

SECTION 1 Instructions for completing the FORM FDA-766 are found on pages 3 and 4.

1. TO: Director of _____ Division, Food and Drug Administration Application is hereby made for authorization to bring the article(s) below into compliance with the Federal Food, Drug, and Cosmetic Act and other related Act(s).	2. APPLICATION DATE	3. ENTRY NO. AND LINE NO.
	4. PRODUCT	
	5. QUANTITY	
6. QUANTITY TO BE RECONDITIONED	7. PRODUCTION CODES	

8. Redelivery bond has been posted by the applicant. The article(s) will be kept apart from all other article(s) and will be available for inspection at all reasonable times. The operations, if authorized, will be carried out at:

and will require about _____ days to complete. A detailed description of the method by which the article(s) will be brought into compliance is given in the space below:

We will pay all supervisory costs in accordance with current regulations.

9. APPLICANT AND FIRM NAME	10. ADDRESS OF FIRM
11. APPLICANT'S SIGNATURE	

SECTION 2 - FDA ACTION ON APPLICATION

12. TO: *(Name and Address)*	13. DATE

14. Your application has been: ☐ Denied because: ☐ Approved with the following conditions:

Time limit within which to complete authorized operations: _____

When the authorized operations are completed, fill in the importer's certificate on the reverse side and return this notice to this office.

15. SIGNATURE OF DIVISION DIRECTOR	16. DIVISION	17. DATE

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SECTION 3 - IMPORTER'S CERTIFICATE

18. Location where reconditioning operation occurred	19. DATE

20a. I certify that the work to be performed under the authorization has been completed and the article(s) are now ready for inspection at: _____

20b. Contact Information: _____

21. The rejected portion is ready for the approved disposition under FDA or CBP supervision and is held at:

22. APPLICANT AND FIRM NAME	23. APPLICANT'S SIGNATURE

SECTION 4 - REPORT OF INVESTIGATOR / INSPECTOR

TO PORT DIRECTOR OR DIVISION DIRECTOR	24. DATE *(MM/DD/YYYY)*

25. I have examined the within-described article(s) and find them to be the identical article(s) described herein, and that they have been:

_____ on: _____, 20 ____,

as authorized, except:

SECTION 5 - DATA ON RECONDITIONED ARTICLE(S)

26. Acceptable Portion:

27. Rejections:

28. Loss (if any):

29. Did importer recondition entire shipment?

30. Time and cost of supervision:

31. INSPECTING OFFICER NAME	32. DATE *(MM/DD/YYYY)*

33. INSPECTING OFFICER SIGNATURE

Instructions for Completing FORM FDA 766 (Reconditioning Proposal)

APPLICATION FOR AUTHORIZATION TO RELABEL OR RECONDITION NON-COMPLIANT ARTICLES

The following instructions can be used by Industry and FDA field staff when requesting and processing requests to recondition FDA regulated products that have been detained due to a violation of the Act. Please note that it is no longer necessary to submit the form in triplicate.

PAGE 1 OF FORM FDA 766:

SECTION 1: To be completed by the Importer of Record

1. To: DIRECTOR: Enter the name of the Food and Drug Administration Division Office that will be receiving the reconditioning proposal.
2. APPLICATION DATE: Enter the date of the proposal in MM/DD/YYYY format.
3. ENTRY NO. AND LINE NO. Enter the applicable entry number and line number. (Please note that adding the line information is important. Ex. Format: 123-4567891-9/11-1)
4. PRODUCT: Enter product name as it appears on the label and brief description of the product.
5. QUANTITY: Enter the total quantity of product.
6. QUANTITY TO BE RECONDITIONED: Enter the quantity of product to be reconditioned.
7. PRODUCTION CODES: Enter the production code or other unique identifiers. (Ex. Lot numbers, expiration dates, production codes and specific quantities to be reconditioned)
8. Enter the following in box #8:
   - The name and address of the location where reconditioning operations will take place: (Include contact information, name and phone number, and the complete name and address of the location.)
   - The approximate time (in days) it will take to complete the reconditioning operations.
   - A detailed description of the method by which the merchandise will be brought into compliance. If additional space is needed, attach the additional documentation to the form. Documentation may include the following: labeling, photographs, private laboratory information.
9. APPLICANT AND FIRM NAME: Enter the name of applicant and firm requesting the reconditioning proposal. This will usually be the individual/firm that will be billed for the supervisory costs.
10. ADDRESS OF FIRM: Enter the firm address that is requesting the reconditioning proposal.
11. APPLICANT'S SIGNATURE: Signature of applicant requesting the reconditioning proposal.

SECTION 2 - FDA ACTION ON APPLICATION: To be completed by the FDA Compliance Officer

12. TO: Enter the name and address identified in 9. and 10. above.
13. DATE: Enter date of action on application in MM/DD/YYYY format. (EX: 11/12/2019)
14. Denied/Approved:
    - Mark the “Denied because:” box if the application is denied. Enter the reason for the denial in the space below.
    - Mark the “Approved with the following conditions:” box if the application is approved. Enter any conditions on which the application was approved in the space below.
    - Add the statement in the box: “ARTICLES SHOULD BE HELD INTACT PENDING THE RECEIPT OF FDA'S RELEASE NOTICE.”
    - Add the current hourly and mileage rates for supervision per 21 CFR 1.99. (Note: this is not an estimation of the total cost of supervision.)
    - Enter time limit within which the Importer has to complete the authorized reconditioning operations. (Enter the date as indicated on the Notice of FDA Action authorizing the reconditioning operations.)
15. SIGNATURE OF DIVISION DIRECTOR: Signature of official authorizing or denying the reconditioning proposal. This is often the compliance officer. May be signed electronically.
16. DIVISION: Enter the FDA Division office approving or denying the reconditioning proposal.
17. DATE: Enter the date the reconditioning proposal was approved or denied in a MM/DD/YYYY format. (EX: 11/12/2019)

PAGE 2 OF FORM FDA 766:

SECTION 3 - IMPORTER'S CERTIFICATE: To be completed by the Importer of Record when the authorized reconditioning operations have been completed.

18. Location where reconditioning operations occurred: Enter the location where the reconditioning operations occurred. This is usually the same location as box 8 on page 1.

19. DATE: Enter the date the reconditioning operations were completed in a MM/DD/YYYY format (EX: 11/12/2019)

20a. Enter the location where the reconditioned goods are ready for inspection if different than location specified in box 18.

20b. Contact information: Enter the contact information for the location where goods are ready for inspection.

21. Enter the location, if necessary, where the rejected portions are held if different than the location specified in box 20. (If different than location where goods are ready for inspection).

22. APPLICANT AND FIRM NAME: Enter name of applicant/importer that is certifying reconditioning operations were performed as authorized.

23. APPLICANT'S SIGNATURE: Signature of applicant/importer.

SECTION 4 - REPORT OF INVESTIGATOR/INSPECTOR: To be completed by FDA Investigator/Inspector or individual verifying the reconditioning was completed.

24. DATE: Enter the date of investigator's/inspector's report in a MM/DD/YYYY format. (EX: 11/12/2019)

25. Enter the results of the field examination and whether they were reconditioned as authorized.

- Enter the month, day and year of the examination of the goods in the spaces provided.
- In the space provided, enter or describe any discrepancy observed during the field examination of the reconditioned goods.

SECTION 5 - DATA ON RECONDITIONED ARTICLE(S): To be completed by FDA Investigator/Inspector or individual verifying the reconditioning was completed.

26. Acceptable Portion: Enter the quantity of the portion reconditioned successfully.

27. Rejections: Enter the quantity of the portion that was not reconditioned successfully.

28. Loss (if any): Enter any losses.

29. Enter response to question “Did importer recondition entire shipment?”

30. Enter time, mileage, and cost of supervision for all applicable FDA staff. (See RPM Section “Supervisory Charges”). Refer to OASIS screen, “Reconditioning Results - Detail Supervision Costs.”

31. INSPECTING OFFICER: Enter the name of the FDA inspecting officer.

32. DATE: Enter the date of inspection of cleaned goods in a MM/DD/YYYY format. (EX: 11/12/2019)

33. INSPECTING OFFICER SIGNATURE: Enter the signature of the FDA inspecting officer.