DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Tobacco Products

Report of Tobacco Product Removals Subject to Tax
for Tobacco Product User Fee Assessments
(Section 919 of FFDCA; Title 21, Code of Federal Regulations, Part 1150)

Form Approved: OMB No. 0910-0749
Expiration Date: 8/31/2022
(See PRA Statement on page 2)

The authority for collecting the following information is section 301 et seq. of the Federal Food, Drug, and Cosmetic Act. The information will be used to assess and collect user fees from tobacco product domestic manufacturers and importers. Please be advised that under section 1001 of title 18 anyone who makes a materially false, fictitious or fraudulent statement is subject to criminal penalties.

Return this completed form and copies of supporting documents (TTB Forms 5220.6, 5210.5 and 5000.24 and Customs CBP Form 7501, as appropriate) to:

Email: TobaccoUserFees@fda.hhs.gov (preferred method)

Fax: 301-595-1429 or 301-595-1430

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Attn: OM, Division of Financial Management, User Fee Team
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

1.A. Company Name and Mailing Address *(including Zip Code)*	1.B. Alternate Company Mailing Address *(if any)*
2. Employer Identification Number (EIN)	3. Contact Person Name
4. Telephone Number *(including Area Code)*	5. Email (for all FDA communication)
6. TTB Permit Number (list all current permits reported on this form)	7. Final Report (list applicable permit) ☐ Check here if this will be your final report to the FDA (i.e., you have returned your permit to TTB or closed your business). Attach relevant documentation with date of closure.

8. Period of Activity (month/year of reported removals)

8.A. Month: _____ 8.B. Year: _____

Privacy Act Notice:

This notice is provided pursuant to the Privacy Act of 1974, 5 U.S.C. 552a. The collection of this information is authorized by 21 U.S.C. 371, 379, 379e, 379h, 379h-1, 379j, 379j-12, 379j-21, 387s and 393(d)(2); 42 U.S.C. 263b(r)(1); 5 U.S.C. 301 and 552; and 42 U.S.C. 3101. FDA will use the information to assess, collect and process user fee payments and to facilitate debt collection under the Debt Collection Improvement Act. FDA may disclose information to courts and the Department of Justice in the context of litigation and requests for legal advice; to other Federal agencies in response to subpoenas issued by such agencies; to HHS and FDA employees and contractors to perform user fee services; to the National Archives and Records Administration and General Services Administration for records management inspections; to the Department of Homeland Security and other Federal agencies and contractors in order to respond to system breaches; to banks in order to process payment made by credit card; to Dun and Bradstreet to validate submitter contact information, and to other entities as permitted under the Debt Collection Improvement Act. Furnishing the requested information is mandatory. Failure to supply the information could prevent FDA from processing user fee payments. Additional detail regarding FDA's use of information is available online: http://www.fda.gov/RegulatoryInformation/FOI/PrivacyAct/default.htm, and http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm

REPORT OF TOBACCO PRODUCT REMOVALS SUBJECT TO TAX

TOBACCO PRODUCT	MANUFACTURER ACTIVITY		IMPORTER ACTIVITY	
	Removal Volume *(in sticks or pounds)*	Excise Taxes *(in dollars)*	Removal Volume *(in sticks or pounds)*	Excise Taxes *(in dollars)*
Cigarettes	9.A.	9.B.	9.C.	9.D.
Cigars	10.A.	10.B.	10.C.	10.D.
Snuff	11.A.	11.B.	11.C.	11.D.
Chewing Tobacco	12.A.	12.B.	12.C.	12.D.
Pipe Tobacco	13.A.	13.B.	13.C.	13.D.
Roll-Your-Own Tobacco	14.A.	14.B.	14.C.	14.D.

15. CERTIFICATION

I hereby certify that the information on this form is true and correct and that I am hereby authorized to submit this form on the company's behalf.

15.A. Print Name	15.B. Title
15.C. Signature	15.D. Date Prepared (mm/dd/yyyy)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 4 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following address:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRASTAFF@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

GENERAL INSTRUCTIONS

Block 1.A. and 1.B.: This includes the primary (and alternate, if any) mailing address for the company holding the TTB permit(s) where the company will receive communication via mail from the FDA to include, but not limited to, notifications and invoices.

Block 6.: List the current, active permits being reported; this should include all permits reported on the applicable form (for example, manufacturer and importer permits should both be listed if reporting on the same form).

Block 7.: Check this box only when the TTB permit(s) is no longer active (e.g., you have returned the permit to TTB, your permit has otherwise closed/expired, or you have closed/dissolved your business). If there are multiple permits and the company is not closing all of them, indicate in block 7 for which permit a final report is being submitted. When checking this box, we suggest the company include documentation showing the permit is no longer active or the company has closed. This can include, but is not limited to: state documents showing the closure or dissolution of the business holding the TTB permit, bond expiration or termination letter, document(s) showing the company returned the permit to TTB and requested closure/termination, etc.

Block 8.A. and 8.B.: This should reflect the month and year associated with the removal data (not the month the submission is due) and should coincide with the dates listed on the supporting documents. For example, monthly submissions are due February 20th for January removal data; therefore, the period of activity for the submission due in February should list January in block 8.A. along with the appropriate year in block 8.B.

Page 2, Column A (Manufacturer Removal Volume): Enter the volume (i.e., gross removal amount) for the period of activity by tobacco class in sticks or pounds. The numbers in this column should reflect the total of the volume reported on TTB 5210.5 line 14, plus the volume reported on TTB 5210.5 line 17, and—when identifiable—plus/minus the volume associated with any Schedule A and B adjustments impacting gross removals (such as over/under payments, shortages disclosed by inventory, under/over-fills, etc.). This does not include claims for withdrawn product. Companies should amend monthly reports to include adjustments in the month they occurred, not necessarily the month the adjustment was reported to TTB.

Page 2, Column B (Manufacturer Excise Taxes): Enter the total excise tax amount for the period of activity by tobacco class in dollars; do not round. This includes the excise tax amounts reported on TTB 5000.24 lines 12, 13, 15, 16 plus/minus the excise taxes associated with any Schedule A and B adjustments by tobacco class impacting gross removals (such as over/under payments, shortages disclosed by inventory, under/over-fills, etc.). This does not include claims for withdrawn product. Companies should amend monthly reports to include adjustments in the month they occurred, not necessarily the month the adjustment was reported to TTB.

Page 2, Column C (Importer Removal Volume): Enter the total volume for the period of activity by tobacco class in sticks or pounds. This includes the total volume reported across all CBP 7501 forms (block 31) for the applicable period of activity. While the volume is reported in thousands of sticks or kilograms on the CBP 7501 form, report the total here as sticks or pounds.

Page 2, Column D (Importer Excise Taxes): Enter the total excise tax amount for the period of activity by tobacco class in dollars; do not round. This includes the total excise tax amount reported across all CBP 7501 forms (block 38) for the applicable period of activity. This total does not include other duties and fees reported on the CBP 7501 (e.g., block 37 and 39).