DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

User Fee Payment Refund Request

Form Approved: OMB No. 0910-0805 Expiration Date: November 30, 2024 See PRA Statement on page 4.

User Fee Payme	nt Ketu	ına ı	Request	L .	See	PRA Statement on page	4.
Section A: Organization Information							
1. Date of Request (mm/dd/yyyy)							
O Constitution Name							
2. Organization Name							
3. Organization Address							
Address 1 (Street address. No P.O. Boxes allowed)							
Address 2 (Apartment quite unit building floor etc.)							
Address 2 (Apartment, suite, unit, building, flo	oor, etc.)						
City	State/Province/Region						
Country		∠IP or	ZIP or Postal Code				
4. Type of Vendor (Select applicable)	5. TII	N/EIN	(Nine-digit nu	mber required i	 for all U.S	. vendors.) Without this en	itry,
U.S. vendor Foreign vendor refund cannot be processed.					_	,	<u></u>
6. DUNS (Nine-digit number required for all							
foreign vendors. See instructions for additional information.) Without this entry, refund cannot gov/portal/public/SAM/ and register with Central Contractor Registration (CCF)							
be processed. CCR electronically validates registrant information and shares the encrypted securely with the FDA. For questions about CCR, call (334) 206-7828.							
	36	curery	with the FDA	rui questions	about CC	N, Call (334) 200-7020.	
Section B: Contact Information 7. Contact Name			8 Contact T	Title/Position			
7. Contact Name			8. Contact Title/Position				
9. Contact Phone Number (Include area code)			10. Contact Email Address				
Section C: Payment Information							
11. Payment Amount			12. Payment Reference Number				
13. PIN or Invoice Number			14. Refund Amount				
15. Is this a FURLS refund request? (See instr	ructions for r	nore ir	nformation.)	Yes	☐ No	(Proceed to field 16)	
(a) FURLS Request Type (b) Registration					or Owner	/Operator Number	
	PIN (Procee	d to fie	eld 16)				
(c) Why did your facility originally pay the fee	?						
(d) Why do you believe your facility is not req	uired to pay	the fee	e?				
(e) List all activities performed at your facility							

Section C: Payment Information (Continued)				
15. Is this a FURLS refund request? (Continued)				
(f) List all products manufactured at your facility				
16. Reason for Request (Please explain)				
17. ACKNOWLEDGEMENT: By signing this document I execute this request on behalf of my organization. A contact information provided.				
18. Signature		Date of Signature (mm/dd/yyyy)		
To enable the signature field, please fill out all prior require which have not yet been filled out, please click here.	ed fields. For a list of required fie	lds		
Section D: FDA Acknowledgement				
19. FDA Received Date (mm/dd/yyyy)	20. Center Decision Approved Denied			
21. If Denied, State Reason				
22. Decision Date (mm/dd/yyyy)	23. Center Contact Name			
	OFM Use Only			
24. Request Executed? 25. If No, State Reason Yes No	·			
26. Final Action Completed – Refunded Complete	27. Date of Final Action (mm/dd/yyyy)			
28. OFM Contact Name				
	·			

Instructions for Completing User Fee Payment Refund Request – Form FDA 3913

Form FDA 3913 is to be completed online at http://www.fda.gov/forindustry/userfees/default.htm and is to be used when requesting the transfer of user fee payments received by the FDA. If you need assistance in completing this form contact the User Fee Helpdesk via phone at (301) 796-7200 or email userfees@fda.gov.

Section A: Payment Information

- 1. **Date of Request:** Enter calendar date the form is being completed.
- 2. **Organization Name:** This is name of the organization submitting the request.
- 3. **Organization Address:** Enter the following elements of the organization's address.

Address 1 – Enter organization's physical street address where the refund is to be sent. <u>No P.O. Boxes are allowed.</u>

Address 2 – As needed, enter apartment, suite, unit, building, floor, etc.

City – Enter the city where organization is located.

State/Province/Region – Enter the state, province or region where organization is located.

Country – Enter country where organization is located.

ZIP or **Postal Code** – Enter zip code or postal code of the organization's location.

Instructions (Continued)

- 4. **Type of Vendor:** Select the appropriate box to indicate whether the organization is a U.S. or foreign vendor.
- TIN/EIN: (U.S. vendor only) Enter organization's nine-digit federal Taxpayer Identification Number (TIN) or Employer Identification Number (EIN). Without this entry, the refund request cannot be processed.
- 6. **DUNS:** (Foreign vendor only) Enter organization's nine-digit Dun & Bradstreet Data Universal Numbering System (DUNS) number. If you do not know your DUNS number or need to request one, visit www.dnb.com or call (800) 234-3867. Without this entry the refund cannot be processed.

Section B: Contact Information

- 7. **Contact Name:** Enter the name of the person requesting the refund.
- 8. **Contact Title/Position:** Enter the position/title of the person requesting the refund.
- Contact Phone Number: Enter the phone number of the person requesting the refund.
- 10. **Contact Email Address:** Enter the email address of the person requesting the refund.

Section C: Payment Information

- Payment Amount: Enter the amount (in U.S. Dollars) of the original payment issued to the FDA.
- 12. Payment Reference Number: If payment was remitted via check, money order or bank draft, enter the check or money order number; if made electronically via Automated Clearing House (ACH) or credit card, enter the confirmation number; if made via wire transfer, enter the trace or Input Message Accountability Data (IMAD) number.
- 13. **PIN or Invoice Number:** Enter the Payment Identification Number (PIN) or invoice number where payment was applied.
- 14. **Refund Amount:** Enter the amount (in U.S. Dollars) that is to be refunded.
- 15. Is this a FURLS refund request? If request is for fees paid for registration within the FDA Unified Registration and Listing System (FURLS), check the appropriate box. If response is "Yes", complete fields (a) through (f). If response is "No", proceed to field 16.
 - (a) FURLS Request Type Check "Used PIN" if PIN was used to register your facility with FDA's

- Center for Devices and Radiological Health (CDRH). Check "Unused PIN" if PIN was not used to register, and proceed to field 16.
- (b) Registration or Owner/Operator Number – Enter FURLS registration or owner/ operator number.
- (c) Why did your facility originally pay the fee? Provide reason why the user fee was paid.
- (d) Why do you believe your facility is not required to pay the fee? Provide reason why the facility should not be required to pay the fee.
- (e) List all activities performed at your facility Provide list of all activities currently performed at your facility (i.e. manufacture medical device, contract sterilizer, etc.).
- (f) List all products manufactured at your facility Provide list of all products associated with each activity.
- Reason for Request: Provide a brief description of why refund is being requested.
- 17. **Acknowledgement:** Review acknowledgment, confirming that you are the authorized representative listed on this form and have provided valid contact information in the event that there are questions pertaining to the request.
- 18. **Signature**: Place signature of listed authorizing official here.

Date of Signature – Date document is signed by authorizing official.

Section D: FDA Acknowledgement

This section is for FDA use only. An FDA representative will fill out the following items:

- 19. **FDA Received Date:** Enter date that request was received by FDA.
- 20. **Center Decision:** Check appropriate box, indicating if request was approved or denied.
- 21. **If Denied, State Reason:** If response to field 20 was "Denied", provide reason.
- 22. **Decision Date:** Enter date decision was made.
- 23. **Center Contact Name:** Enter name of the Center's action officer.
- 24. **Request Executed:** Check the appropriate box, indicating if request was executed.
- 25. **If No, State Reason:** If response to field 24 was "No", provide reason.

Instructions (Continued)

- 26. **Final Action:** Check the appropriate box, indicating if request was refunded or not refunded.
- 27. **Date of Final Action:** Enter date that final action was taken on request.
- 28. **OFM Contact Name:** Enter name of the OFM action officer.

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 0.40 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:

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."