



FDA CIRCULAR
No. 2021-027

31 DEC 2021

TO : ALL CONCERNED STAKEHOLDERS
SUBJECT : Revised Guidelines for Transfer or Refund of Payments Made to the Food and Drug Administration

1. BACKGROUND

The Food and Drug Administration (FDA), in the exercise of its functions, issues license, permits, and certifications to establishments engaged in the manufacture, distribution, trade, and/or sale of health products and for products that are placed in the market. These services involve the consumption of resources that entail additional cost and expenditure to the agency. As such, the agency uses charges and fees to fund its services. In cases where there are overpayments or erroneous payments made by a client due to circumstances beyond their control and with no contributing negligence, the agency shall provide opportunities to refund and transfer payments made.

2. OBJECTIVE AND SCOPE OF APPLICATION

This Order aims to guide all concerned stakeholders on claiming of refunds and transfers of payments made in all FDA Offices (i.e. Alabang Central Office, Regional Field Offices, and Satellite Laboratories) and authorized payment channels for services rendered by the agency.

3. GENERAL GUIDELINES

- 3.1. These guidelines shall be for strict compliance. Failure of the applicant, or his duly authorized representative, to abide with these guidelines shall be deemed a waiver of the right to file for refund or transfer.
- 3.2. Requests found to have failed compliance to the provisions of this Circular shall not be given due course, and shall be subjected to subsequent denial, including all future instances on the same subject of the request for transfer or refund.
- 3.3. Requests for transfer or refund must be filed within 90 days of payment. Failure to file a Request shall be deemed as a waiver of the applicant's right to file for refund or transfer, as the case may be. All requests for transfer or refund shall be coursed through the Food and Drug Administration Action Center (FDAC).



- 3.4. Requests for transfer or refund found non-compliant to these guidelines, or submitted beyond the 90-day period, shall be subject to summary denial.
- 3.5. In the absence or failure to duly file a letter-request for refund or transfer, payments made pursuant to such transactions by the applicant or his duly authorized representative shall thus be subject of forfeiture by the FDA.
- 3.6. Requests for refunds and transfer of payments shall not be allowed for any applications (LTO, CPR, Variations and other fees) in cases where services have already been rendered by FDA, even if the application have been cancelled or discontinued.

4. SPECIFIC GUIDELINES

A. REFUND

- 4.1. In meritorious circumstances, the FDA may grant requests for **refund** through the issuance of a *Certificate of Credit* for payments made, subject to existing laws, accounting and auditing rules, and procedures, as may be applicable. After evaluation and verification of the request, the FDA may grant the applicant either a **full or partial refund** of their payment.
- 4.2. A certificate of credit may be issued in the following circumstances:
 - 4.2.1. **Overpayments** made as a result of miscalculated fees with no fault on the part of the client;
 - 4.2.2. Payments made for applications **mistakenly filed for discontinued services** excluding ePortal applications; and,
 - 4.2.3. Other similar circumstances deemed appropriate as may be determined by the FDA.

B. TRANSFER

- 4.3. Requests for the **transfer of payments made** shall be granted only upon just and valid causes. In no case shall requests be granted when the cause of the erroneous payment was due to the fault or negligence of the payor. Requests for refund may be granted by the Administrative and Finance Service (AFS), through an official duly designated for the matter.
- 4.4. Transfers will be subject to the following:
 - 4.4.1. Payments may only be transferred to transactions within the same Center or Office concerned, where the subject payment was made for.
 - 4.4.2. The request must pertain to a specific receipt. Only one request per receipt shall be entertained.

- 4.4.3. A Single Transfer Transaction may also be made in favor of multiple applications, *provided* that if the subject of the request is “insufficiency of payment(s) made”, additional payment shall first be made in order to cover the insufficiency. In this case, only a one-time transfer shall be allowed.
- 4.4.4. No transfer shall be made where the request is made to circumvent the procedures of the FDA, or change the date of payment to a later date by utilizing the refund/transfer mechanisms.
- 4.5. Transfers requested for reason of transition from the e-Portal System to the eServices System shall be automatically approved, upon proper endorsement of ICTMD and the AFS – Cashier.

5. PROCEDURE

5.1. Procedure in filing refund claims:

- 5.1.1. The applicant, or his duly authorized representative, shall submit a letter–request addressed to the AFS– Chief Accountant, for the refund of the payment made. Such request shall indicate the exact amount paid, along with all supporting details of the payment, including but not limited to the Original Receipt Number or Deposit Transaction Reference Number.
- 5.1.2. The applicant shall also submit copies of the issued original Official Receipt issued by FDA or a copy of the Deposit Slip if payment was made thru a banking facility, or any other documentary evidence showing payment made thru any of the facilities available and recognized by the FDA.
- 5.1.3. The letter–request shall state the reason and/or justification for the grant of the refund, citing specifically the grounds relied on, based from the provision of these guidelines. All requests must be coursed through the FDAC. Once the letter–request has been submitted, the FDAC shall provide an acknowledgement of the letter by providing a Document Tracking Number (DTN) to the client.
- 5.1.4. Validity of claims shall be verified by AFS Accounting and approved by the Chief Accountant, with recommending approval by the AFS Cashier, based on a duly accomplished checklist.
- 5.1.5. If found to be satisfactory, the request shall be approved and forwarded to the FDA Cashier for the facilitation of the refund.

5.2. Procedure in filing Transfer of payment applications:

- 5.2.1. Requests for transfer of payments shall be through a letter–request directed to the AFS– Chief Accountant.
- 5.2.2. Requests shall be strictly coursed through the FDAC. Once the letter–request has been submitted, a DTN shall be provided to the client.

- 5.2.3. The request shall contain a narration of the events necessitating the transfer of payment and/or a valid justification for the grant thereof, with the inclusion of all relevant evidence, including proof of payment.
- 5.2.4. Validity of claims shall be verified by the AFS Accounting Division, through a duly accomplished checklist. The request shall then be recommended for approval by the AFS Cashier, with final approval by the Chief Accountant.
- 5.2.5. If found to be satisfactory, the request shall be approved and forwarded to the FDA Cashier for the facilitation of the transfer of payment.

5.3. Reportorial Requirements

- 5.3.1. The AFS Accounting Division is required to submit a monthly report of all transfer and refund requests made to the Office of the Deputy Director General for Internal management. The report shall indicate whether a request was granted or denied, and the reason therefor.

6. SEPARABILITY CLAUSE

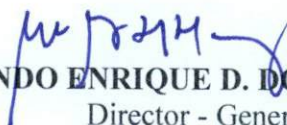
In case any section or provision of this Circular or any part thereof, or the application of such section, provision or portion shall be declared invalid, the validity of the remaining provisions of this Circular shall not in any way be affected or impaired thereby.

7. REPEALING CLAUSE

FDA Circulars 2017-008 and 2017-009 are hereby repealed. Any other Circular, Memorandum, Issuance, Rule and Regulation which are inconsistent with the provisions of this Order are hereby modified or repealed accordingly.

8. EFFECTIVITY

This Order shall take effect immediately.


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Director - General