1. BACKGROUND

The Food and Drug Administration (FDA), in the exercise of its functions, issues licenses, 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 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, the agency shall provide opportunities to refund payments made.

2. OBJECTIVE AND SCOPE OF APPLICATION

This Order aims to guide all concerned stakeholders on claiming of refunds on 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. GUIDELINES

3.1. As a general rule, refunds shall not be allowed for any application (LTO, CPR, Variations and other fees) in cases where services have already been rendered by FDA, even if such application has been cancelled or discontinued.

3.2. In meritorious circumstances, FDA may grant requests for refunds for payments already made subject to existing laws, accounting and auditing rules, and procedures, as may be applicable. FDA may grant a full or partial refund as found after the verification of the request. A certificate of credit may be granted in the following circumstances:

3.2.1. Overpayments made as a result of miscalculated fees with no fault on the part of the client;
3.2.2. Payments made for applications mistakenly filed for discontinued services; and
3.2.3. Other similar circumstances deemed appropriate and without fault on the part of the client as determined by the FDA.

3.3. Claims for Refund must be made within ninety (90) days from the date of payment, otherwise the payment shall be deemed forfeited.

3.4. Procedure in Filing Refund Claims
3.4.1. The authorized representative shall submit a letter addressed to the Director of the Administration and Finance Service (AFS), requesting for issuance of refund payments (Item 3.1.) and indicating the amount paid, attaching the issued original Official Receipt issued by FDA or a copy of the Deposit Slip. Such letter shall also include a valid justification for the grant of the refund. It must be received through the Food and Drug Action Center (FDAC), formerly known as the PAIR Unit, during the usual business hours.

3.4.2. FDAC shall provide an acknowledgement of the letter by providing a Document Tracking Number (DTN) to the client. The DTN is not to be misconstrued as the approval of the request. It shall merely be used for proper tracking the document.

3.4.3. Validity of claims shall be verified by the Accounting Division of the AFS through a checklist duly accomplished by the concerned Office/Center and approved by the AFS Director.

3.4.4. Upon approval of the claim, the processing of the refund shall be facilitated.

4. SEPARABILITY CLAUSE

   In case any section or provision of this Order 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 Order shall not in any way be affected or impaired thereby.

5. REPEALING CLAUSE

   Any other order, memorandum, issuance, rule and regulation which are inconsistent with the provisions of this Order is hereby modified or repealed accordingly.

6. EFFECTIVITY

   This Order shall take effect immediately.

   NELA CHARADE G. PUNO, RPh
   FDA Director General