Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. _____

SUBJECT: **Implementing Guidelines for Imported Pharmaceutical Products from a Foreign Trader**

I. RATIONALE/BACKGROUND

Throughout the implementation of Administrative Order No. 2013-0022 "Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers", it was found that certain drug products were identified to be reflecting the loan licensee as the manufacturer in its labeling materials as per the approved Certificate of Product Registration (CPR).

In third-party/contract manufacturing, the marketing company contracts a third-party manufacturing company to manufacture their product, reflecting the actual manufacturing and marketing company in the labeling materials and product dossier. In a loan license, the marketing company avails itself the manufacturing facilities of the manufacturing company, providing some or all of the complete manufacturing process, equipment, personnel, etc., and is reflected as the manufacturer of the product. The marketing company is identified as the loan licensee of the product.

During the evaluation of the renewal registration applications of drug products, it was observed that the CPRs reflecting the loan licensee as the drug manufacturer of the drug product were unable to comply for the submission of the valid Certificate of cGMP Clearance, leading to the delay of the processing of these applications and some leading to an issuance of a Letter of Disapproval.

To align the foreign regulations to the national guidelines of product registration, this Circular is hereby established.

II. DEFINITION OF TERMS

A. Foreign Trader – the marketing company from the country of origin availing the manufacturing facilities of the manufacturing company, either thru third-party/ contract manufacturing or a loan license.

B. Loan License – the license issued to a marketing company that avails the manufacturing facilities owned by a drug manufacturer.

C. Loan Licensee – the marketing company, issued with a Loan License by the national regulatory authority from the country of origin.

III. OBJECTIVES

This Circular aims to:

A. Provide guidelines to reflect the actual manufacturer of drug products;
B. Provide guidelines for all renewal, compliance, MR to Initial Applications which were disapproved due to non-submission of the Foreign current Good Manufacturing (cGMP) Clearance due to the reflected manufacturer is a loan license manufacturer; and
C. Provide guidelines to all pending and incoming registration of drug products having a foreign trader.

IV. SCOPE

This Circular shall apply to all drug products having a Foreign Trader.

V. IMPLEMENTING DETAILS

A. General Guidelines

1. All drug products are required to declare their actual manufacturers and manufacturing sites in their dossiers and labeling materials.
2. The loan licensee shall be categorized and be reflected as the Foreign Trader to all market authorizations issued by this Office.

B. Specific Guidelines

1. Drug products with valid CPR

   All drug products with a valid CPR reflecting the loan licensee as the drug manufacturer shall apply for Minor Variation – Prior Approval within the validity of their CPR:

	Change to reflect the actual manufacturer from the loan licensee; Reflect Foreign Trader
Condition (C)	1. No change in the actual manufacturer of the drug product.
Documents (D)	1. Authenticated Manufacturing License or any official document from relevant authority indicating that the current manufacturer is a loan licensee; 2. Valid Certificate of Foreign cGMP Clearance or proof of application for initial or renewal; and 3. Currently approved product labeling. 4. Proposed product labeling, a clean and annotated version highlighting the changes made

	5. Certificate of Pharmaceutical Product reflecting the actual manufacturer and foreign trader

2. Disapproved renewal, compliance, and Monitored Release (MR) to Initial applications

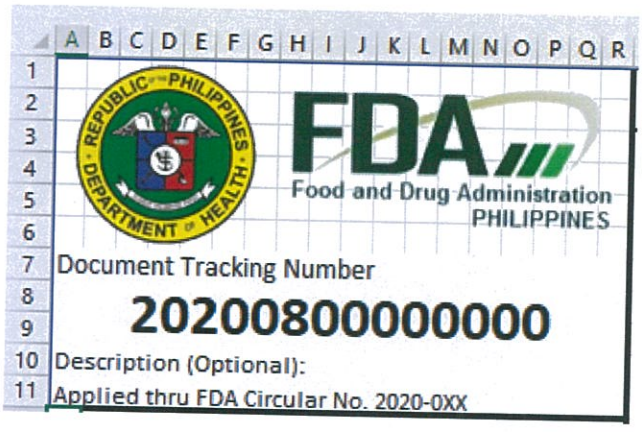
   a. Drug products with renewal, compliance, and MR to Initial applications disapproved due to failure to the provide the Certificate of Foreign cGMP Clearance since the manufacturer reflected on the CPR was the loan licensee, may apply for appropriate application to renew their validity, provided that the application shall be filed within one hundred twenty days (120) days from the date of expiry.

   b. Drug products with renewal and compliance applications disapproved and are beyond the 120 days from the date of expiry shall apply for initial product registration following the prescribed requirements for initial registration and fees equivalent to the total surcharge or penalty plus the initial filing fee.

      i. For disapproved MR to Initial applications that are beyond the 120 days from the date of expiry, they shall apply for the MR to Initial registration application following MR to Initial fees and requirements.

      ii. Applications filed under Section V.B.2.b. of this Circular shall indicate under the Description of the Integrated Application Form "Applied thru FDA Circular No. 2020-0XX".

      e.g.



3. Drug Products with Pending Applications

   a. All pending applications of renewal, compliance, and MR to Initial that has failed to submit a Certificate of GMP Clearance due to the reflected manufacturer is a loan license manufacturer shall be issued with a CPR reflecting its full validity. The applicant shall apply within two years from the date of issuance of the CPR for post-approval change following the provisions of Section V, B, 1 of this Circular.

b. All pending applications for initial or MR registration shall be reviewed to identify the actual manufacturer of the product. Non-submission of the Certificate of GMP Compliance of the actual manufacturer shall result to the disapproval of the application.

4. Incoming Initial and MR Applications

All incoming applications for Initial and MR registration shall declare the actual manufacturer and its address and provide corresponding agreements if the product is under foreign trader. Failure to comply shall be a ground for the disapproval of the product registration.

VI. REPEALING AND SEPARABILITY CLAUSE

Provisions in previous circulars and memoranda that are inconsistent with this Circular are hereby withdrawn, repealed and/or revoked accordingly.

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Circular shall not be affected.

VII. EFFECTIVITY

This Circular shall be effective immediately.

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Director General

Keywords	Loan License, Loan Licensee, Manufacturer, Foreign Trader
Related Issuances, laws, directives from other government agencies	RA 9711, AO 2013-0022, AO 2016-0008