Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA
Food and Drug Administration
PHILIPPINES

20 JUL 2017

FDA CIRCULAR
No. 2017 004

SUBJECT: **Reiteration of the Rule on Licensing Applications Requiring Prior Inspection Pursuant to Administrative Order No. 2016-0003 dated February 15, 2017**

I. INTRODUCTION

Section 3 of Republic Act No. 9711 or otherwise known as the Food and Drug Administration Act of 2009, has declared it a policy of the State to adopt, support, establish, institutionalize, improve, and maintain structures, processes, mechanisms, and initiatives that are aimed, directed, and designed to help establish and maintain an effective health products regulatory system.

Republic Act No. 9485 or otherwise known as the Anti-Red Tape Act of 2007 was enacted to improve efficiency in the delivery of government services and to establish effective practices aimed at the prevention of graft and corruption in the government. Section 5 thereof expressly mandates all offices and agencies which provide frontline services to regularly undergo evaluation and improvement of their transaction systems and procedures and re-engineer the same if deemed necessary to reduce bureaucratic red tape and processing time.

Currently, the Food and Drug Administration's (FDA) Citizen Charter on Licensing Procedure provides that the duration of the process for the issuance of the License to Operate (LTO) is approximately thirty (30) days for compliant applications. Following the above-mentioned policies and mandates this Circular is hereby issued.

II. OBJECTIVES

This Circular is issued to rationalize and reiterate the scope of licensing applications requiring prior inspection, and to further provide coherence in the FDA's regulatory system for covered establishments.

III. SCOPE

This Circular shall apply to initial applications for LTO and Major Variations applications filed by manufacturers of health products. It shall likewise apply to all Food-Drug Regulation Officers of the FDA.

IV. APPLICABILITY

Consistent with Administrative Order No. 2016-0003 dated February 15, 2017 providing for the "Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration (FDA)", prior inspection is only required on the following applications of manufacturers of health products:

1. *Initial application*
2. *Major variation application*
3. *Renewal application coupled with a major variation*

Provided, that for major variation application of manufacturers, the inspection covers only the declared variation.

For any major variation applications of establishments other than manufacturers, post-licensing inspection shall apply.

V. REPEALING AND SEPARABILITY CLAUSE

Provisions of existing FDA Circulars or Memoranda that are inconsistent with this Circular are hereby withdrawn, repealed and/or revoked accordingly.

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

VI. EFFECTIVITY

This Circular shall take effect immediately.

NELA CHARADE G. PUNO, RPh
Director General