



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER

No. 2014 - _____

SUBJECT: Revised Rules and Regulations on the Registration of Over-the-Counter (OTC) Drug Products for Human Use

I. BACKGROUND/RATIONALE

Section 15, Article II of the 1987 Constitution declares it a policy of the State to protect and promote the right to health of the people and instill health consciousness among them.

Republic Act No. 3720, otherwise known as the "Foods, Drugs and Devices, and Cosmetics Act", as amended, and Republic Act No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", and its Implementing Rules and Regulations were enacted to establish an effective regulatory system for the registration and monitoring of health products, including pharmaceutical products.

Administrative Order No. 23-C s. 2000, "Policies and Guidelines on Over-the-Counter Drug Products" was issued to promote greater accessibility to drug products by allowing certain drug products to be dispensed even without a prescription. At the same time, the said regulation provided safeguards to ensure that though these drugs are easily accessible, safety is assured. Other safeguards were also instituted by FDA: labeling standards – to ensure that the total information necessary to guide the public to make an informed decision; pharmacovigilance program – to serve as feedback mechanism for post-marketing surveillance of these products; risk management plan – to serve as contingency plan should the safety, efficacy, and/or quality of the drug product be compromised.

However, with the emergence of safety issues from these supposedly safe OTC products, coupled with the strengthening of pharmacovigilance worldwide, and the recent issuance of regulations promoting rational drug use, there is a need to revise the existing rules and regulations governing OTCs.

II. OBJECTIVES

The general objectives of this Administrative Order are (1) to promote the rational use of drugs and (2) rationalize the existing rules and regulations governing OTC drug products.

More specifically, this Administrative Order aims to:

- 1) Update the regulations on classifying OTCs to prescription drug products, and vice versa; and
- 2) Implement strict monitoring on the promotion, distribution, dispensing, and use of OTC drug products.

For purposes of this Administrative Order, over-the-counter (OTC) drugs products are drug products for human use that can be dispensed even without the written order or prescription of a licensed physician or dentist for the symptomatic relief of minor or self-limiting ailments. These drug products shall be sold only in FDA licensed drug outlets.

III. SCOPE

This Administrative Order shall apply to all drug establishments and outlets engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, dispensing, donation, transfer, use, testing, promotion, advertising, or sponsorship of OTC drug products.

IV. IMPLEMENTING DETAILS

A. Authority to Classify/Reclassify Drug Products as OTC

FDA, as the National Regulatory Authority shall have the authority to review and classify or reclassify a drug molecule as OTC or prescription drug.

B. List of OTC Drug Products

- 1) Review Drug Products to classify as OTC or prescription drug

FDA shall conduct a review process of existing registered drug molecules in a specified dosage form which shall be classified/reclassified as an OTC or prescription drug. In the review and classification process, FDA shall use the best evidence available, which may include, but not limited to:

- a) Meta analyses
- b) Systematic Reviews
- c) Post Benefit-Risk Evaluation Review
- d) Periodic Safety Update Reports (PSUR)

- e) Post-approval Safety Report (PASS)
- f) Post-approval Efficacy Report (PAES)

In the presence of conflicting evidences, the FDA is hereby authorized to create and seek the guidance of an independent evidence review group (ERG) on their recommendation. The initial list of drug molecules in a specified dosage form classified as an OTC shall be issued in an appropriate regulation to be posted in the FDA website.

2) Additional Drug Products Classified as OTC

Any concerned stakeholder may initiate an appeal or request for a drug molecule to be classified/reclassified as OTC, subject to FDA's approval. The list of documentary requirements for classification/reclassification is attached as Annex A.

The FDA Director General shall issue in an appropriate regulation any molecule that shall be classified/reclassified as OTC.

3) Restrictions to the Classification as OTC

Following the provisions of Republic Act No. 9502, any drug prepared in multiple dosage strengths shall only be under one classification; however, though the classification as an OTC is based on the characteristics of the drug molecule, all parenterals are still classified as prescription-only preparation. No new chemical entities, new drug products, or monitored release applications shall be considered as an OTC.

C. Registration as OTCs

1) Classification/Reclassification

Once a drug molecule in a specified dosage form is classified as an OTC, all market authorization holders (MAH) of existing products are required to apply for post-approval change of their labeling materials (e.g., removal of Rx symbol and Caution statement, revision of product information). MAHs shall be given period of time to revise their labeling materials.

2) Initial Application of OTC

As OTCs are considered low risk products, a reduced quality dossier with an attached Risk Management Plan shall be the requirement for initial registration. However, to ensure safety, efficacy, and quality, the drug product

must be in full compliance with acceptable (1) compendial and (2) OTC monographs.

The following are acceptable compendia, latest edition:

- 1) United States Pharmacopoeia-National Formulary (USP-NF)
- 2) British Pharmacopoeia
- 3) European Pharmacopoeia
- 4) Japanese Pharmacopoeia
- 5) Philippine Pharmacopoeia
- 6) Any other Pharmacopoeia deemed to be acceptable shall be issued in an appropriate regulation.

All quality tests provided in a compendial monograph must be reflected in the Finished Product Specification Sheet. Any revision in a given compendia shall be automatically adopted.

In addition to the requirements of the compendial monograph, the drug product must strictly comply with the requirements of an OTC monograph. FDA is hereby tasked to create an OTC monograph. In the absence of the FDA OTC monograph, applicants must comply with the US FDA OTC monograph described under Chapter I – Food and Drug Administration, Subchapter D, Part 300 -369 of the Code of Federal Regulations insofar as they are not in conflict with the national laws of the Philippines, in which case, the latter shall prevail.

The list of documentary requirement for initial registration of an OTC is attached as Annex B.

If, upon evaluation of the submitted documents, it was found that additional documents are required the applicant company shall be informed in writing.

D. Labeling Requirements

The existing labeling requirements shall apply.

E. Registration Process

The registration/application process shall be as prescribed in the latest issuance of FDA.

F. Fees and Charges

The appropriate fees as prescribed under existing regulations shall apply, including legal research fund (LRF). FDA, from time to time, may prescribe changes in fees, which shall be promulgated in an appropriate regulation.

G. Sale, Distribution and Dispensing

As per existing regulation, the sale and distribution of OTCs are only through FDA duly-licensed outlets.

H. Advertisement and Promotion

As per Administrative Order No. 65 s. 1989 only OTCs may be advertised or promoted in any form of mass media, provided that the content is in accordance with the approved labeling information.

I. Assistance from Other Government Agencies

Consistent with the provisions of Republic Act No. 9711 and its implementing Rules and Regulations, FDA hereby invokes its power to call on the assistance of other government agencies, in particular the Professional Regulation Commission and the different associated Boards.

In addition, the Philippine National Police (PNP) and any other law enforcement agencies are also called for the monitoring of distribution and sale of OTC drugs. PNP and other law enforcement agencies are deputized to report any unauthorized outlets making available these products to the public in violation of existing rules and regulations.

V. TRANSITORY PROVISIONS

Within one (1) year upon the effectivity of this Administrative Order, FDA shall conduct its review of all existing drug molecules for classification/reclassification to OTC. Upon completion, FDA shall issue in an appropriate regulation the initial list of drug molecules classified as OTC.

VI. SANCTIONS

Any violation of this Administrative Order consistent with Republic Act No. 3720 and Republic Act No. 9711 and its implementing rules and regulations shall be a ground for filing of appropriate administrative charges and/or imposition of administrative sanctions such as, but not limited to, imposition of fines, suspension, cancellation or revocation of any license, permit or registration issued by FDA.

VII. REPEALING CLAUSE/SEPARABILITY CLAUSE

Administrative Order No. 23-C s. 2000, as well as other provisions from previous issuances that are inconsistent with this Administrative Order are hereby withdrawn, repealed, and/or revoked accordingly.

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

VIII. EFFECTIVITY

This Order shall take effect after fifteen (15) days following its publication in two (2) newspapers of national circulation and upon filing to the University of the Philippines Law Center-Office of the National Administrative Register.

ENRIQUE T. ONA, MD
Secretary of Health

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ANNEX A

Requirement for Classification from Prescription Only to Over-the-Counter Drug Product

Part I: Administrative Data and Product Information

Sec. A Introduction

Sec. B Table of Contents

Sec. C Guidance on the Administrative Data and Product Information

1. Application Form

2. Certifications

a. Certification from 2 recognized DRAs that the API is classified as an OTC for twenty years

b. Certification from 2 recognized DRAs that the API is neither with bioequivalence (BE) problems nor classified as a prohibited, regulated or an internationally controlled drug product

c. Certification from 2 recognized DRAs that the API has low incidence of ADR

3. Labeling materials of the drug product approved from 2 recognized DRAs

4. Product Information

5.1. Patient Information Leaflet

*Recognized DRA - Australia, Canada, Japan, Sweden, UK, and USA

Part II: Clinical Document

Sec. A Table of Contents

Sec. B Evidence of Safety and Efficacy

1. Pharmacokinetic Studies

2. Pharmacodynamic Studies

3. Confirmatory Pharmacokinetic/Pharmacodynamic Studies

4. Efficacy Studies

5. Safety Studies

7. Extrapolation of Efficacy and Safety Data

ANNEX B

Requirement for Registration of Over-the-Counter Drug Product

- Part I: Administrative Data and Product Information
 - Sec. A Introduction
 - Sec. B Overall Table of Contents
 - Sec. C Guidance on the Administrative Data and Product Information
 - 1. Application Form
 - 2. Letter of Authorization (where applicable)
 - 3. Certifications
 - For contract manufacturing
 - a. License of pharmaceutical industries and contract manufacturer
 - b. Contract manufacturing agreement
 - c. GMP certificate of contract manufacturer
 - For manufacturing "under-license"
 - a. License of pharmaceutical industries
 - b. GMP certificate of the manufacturer
 - c. Copy of "under-license" agreement
 - For locally manufactured
 - a. License of pharmaceutical industries
 - b. GMP certificate (country specific)
 - For imported products
 - a. License of pharmaceutical industries/importer/wholesaler (country specific)
 - b. Certificate of Pharmaceutical Product issued by the competent authority in the country of origin according to the current WHO format
 - c. Site Master File of the manufacturer (unless previously submitted within the last 2 years) (country specific)
 - 4. Labeling
 - 5. Product Information
 - 5.1. Patient Information Leaflet
- Part II: Quality
 - Sec. A Table of Contents
 - Sec. B Quality Overall Summary
 - Sec. C Body of Data
 - Drug Substance (S)
 - S 1 General Information
 - S 1.1. Nomenclature
 - S 1.2. Structural Formula
 - S 1.3. General Properties
 - S 2 Manufacture
 - S 2.1. Manufacturer(s)
 - S 3 Control of Drug Substance

- S 3.1. Specifications
- S 3.2. Batch Analyses

Drug Product (P)

- P 1 Description and Composition
- P 2 Manufacture
 - P 2.1. Batch Formula
 - P 2.2. Manufacturing Process and Process Control
- P 3 Control of Finished Product
 - P 3.1. Specifications
 - P 3.2. Batch Analyses
- P 4 Container Closure System
- P 5 Product Stability