LICENSING OF HEALTH FACILITIES INVOLVED IN THE PRODUCTION OF MEDICAL-GRADE OXYGEN

Center for Drug Regulation and Research
Field Regulatory Operations Office
Media Room, 1st Floor, Main Building
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City
25 September 2014
Presentation Outline

A. Objectives of the Meeting
B. Background
C. FDA Circular 2014-018
D. Existing Licensing Requirements
E. New Licensing Requirements
Presentation Outline

F. Inspection Requirements
G. Registration Requirements
H. Future Directions
I. Discussion
A. OBJECTIVES OF THE MEETING
Objectives of the Meeting

- Provide a brief background on the regulation
- Discuss the licensing requirements
- Solicit feedbacks from hospital operations group
- Provide future directions in the regulation
B. BACKGROUND
Food and Drug Administration

Republic Act No. 9711

Ensure monitoring and regulatory coverage over establishments and products under its jurisdiction
Collection of samples of health products (food, drug, device, cosmetics) [FROO]

analyze and inspect health products [Centers]
Food and Drug Administration

Republic Act No. 9711

- Recommend standards of identity, purity, safety, efficacy, and quality [Centers]
- Issue certificates of compliance as the basis for the issuance of authorization (CPR and LTO) (establishments) [FROO and Centers]
Bureau of Health Facilities and Services

Republic Act No. 4226

- Approval of construction and licensure of hospitals (PTC, LTO, CTO, and COA)
- Inspection of hospitals for their compliance with regulatory standards
- Set standards for regulation of health facilities
“Drugs”

Republic Act No. 9502

- recognized in the USP-NF, HPUS, PP, PNDF, BP, EP, JP, IP, any national compendium or any supplement to any of them;
- intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals

Center for Drug Regulation and Research
Conclusion

- Medical oxygen products – considered drug products
- Under the regulatory jurisdiction of FDA
- Manufacturers – require LTO
- Medical oxygen products – require registration
Triggers

- 2013 – reports re: existence of medical-oxygen generating machines
- Not regulated by FDA/BHFS
- Quality issues-unknown purity and manufacturing process undertaken
Initially reported hospitals

1. Veterans Regional Hospital (R II)
2. Ospital ng Palawan (R IV-B)
3. Culion Sanitarium (R IV-B)
4. Bicol Sanitarium (R V)
5. Southern Philippines Medical Center (Davao Medical Center) (R XI)
6. East Avenue Medical Center (NCR)
Verification

MEMORANDUM

FOR: Dr. MYRIAM C. TABIAN
Licensing Regulation and Enforcement Division (LRED) Chief,
Department of Health – Regional Office II, Cagayan Valley

Dr. CAROL O. MACABEO
LRED Chief, Department of Health – Regional Office IV-B, Mimaropa-B

Atty. EMILIO L. POLIG, JR.
OIC, Regional Field Office (RFO) – National Capital Region (NCR)

Atty. ALEXIS C. ALBAO
LRED Chief, Department of Health – Regional Office V, Bicol

Dr. ANA LIZA C. JABONERO, MPH
LRED Chief, Department of Health – Regional Office XI, Davao Region

FROM: MARIA LOURDES C. SANTIAGO, MSC, MM
Officer-in-Charge, Center for Drug Regulation and Research

SUBJECT: Use of Medical Oxygen Generating Machine in Hospital Facilities
Findings

- 1 hospital procures solely from licensed establishment
- 1 hospital procures but has installed machine
- From Hundredfolds Industries Corp
- **Production scale** – (~70 tanks/day, 24 hr operation)
Republic of the Philippines
Department of Health
Food and Drug Administration

C. FDA CIRCULAR NO. 2014-018
FDA CIRCULAR NO. 2014-018

TO: ALL CONCERNED GOVERNMENT-OWNED AND PRIVATE HOSPITALS, HEALTH FACILITIES, AND OTHER ESTABLISHMENTS

FROM: KENNETH Y. HARTIGAN-GO, MD
Acting Director General, Food and Drug Administration

DATE: 15 August 2014

SUBJECT: MANUFACTURE, SALE, AND DISTRIBUTION OF UNREGISTERED MEDICAL-GRADE OXYGEN
FDA CIRCULAR NO. 2014-018

- Administrative Order No. 2012-0008 – PIC/s-GMP
- Administrative Order No. 56 s. 1989 - Licensing
- PSD02-12 - registration
FDA CIRCULAR NO. 2014-018

- 3 months to apply for licensing and subsequent registration
- Failure to comply – appropriate regulatory action
D. EXISTING INITIAL LICENSING REQUIREMENTS
Initial LTO Application

1. Company Profile
2. Application Form
3. Proof of Business Name Registration
4. Credentials of Pharmacist
5. Proof of Ownership of Business space
6. Financial Statement
7. Location Plan
8. List of Products
9. Site Master File
10. Proof of Payment
Documentary Requirements

(1) Company Profile

Information to the activities of the establishment
Documentary Requirements

(2) Application Form

- Completely filled-up
- signed by the authorized personnel
- duly notarized
Documentary Requirements

(3) Proof of Business Name Registration

- For single proprietorship - Certificate of Business Registration issued by DTI
- For corporation, partnership and other juridical person - Certificate of Registration issued by SEC and Articles of Incorporation
Documentary Requirements

(3) Proof of Business Name Registration

- For cooperative - Certificate of Registration issued by the Cooperative Development Authority and the approved by-laws

- For government-owned or controlled corporation - the law highlighting the provision creating such establishment
Documentary Requirements

(3) Proof of Business Name Registration
Must specify exact and complete address, where applicable:

- unit number
- Floor
- Building
- Lot
- Block

- street
- Phase
- Barangay
- city/ municipality
- province
Documentary Requirements

(4) Credentials of pharmacist

- Valid PRC ID, Registration Board Certificate, PTR

- Certificate of Attendance to Licensing Seminar

- Duties and Responsibilities

- ID picture, including the Owner/Authorized Representative (5x5cm)
Documentary Requirements

(5) Proof of Ownership of Business Space

- **Contract of Lease** if not owned
- **Transfer Certificate Title** if owned
(6) Financial Statement

- Financial statement notarized or received by BIR
- If not available, certification of initial capital invested
Documentary Requirements

(7) Location Plan

• Sketch of the location
• “how to get there”
• Directions with landmarks
• Size of plant
• Description of immediate environment
• Type of building
• GPS Coordinates
Documentary Requirements

(8) List of Products

- Generic and brand name (where applicable)
(9) Site Master File

• Based on PIC/s GMP, following the format provided under Bureau Circular No. 3 s. 2005
Documentary Requirements

(10) Proof of Payment

• OR or payment slip
E. NEW INITIAL LICENSING REQUIREMENTS
Initial LTO Application

1. Application Form
2. Proof of Business Name Registration
3. Credentials of Pharmacist and other Qualified Personnel
4. Risk Management Plan
5. Location Plan
6. Site Master File
7. Proof of Payment
8. Self-Assessment Toolkit
Documentary Requirements

(3) Credentials of pharmacist and other qualified personnel

- For pharmacist
  - Valid PRC ID
  - Certificate of Attendance to Licensing Seminar
Documentary Requirements

(3) Credentials of pharmacist and other qualified personnel

- For other qualified personnel
  - CV
  - Training records to prove qualification
Documentary Requirements

(3) Credentials of pharmacist and other qualified personnel

Qualified personnel

• production manager
• quality assurance manager
• quality control manager
• authorized person for batch release
Documentary Requirements

(4) Risk Management Plan

Details on:

• **identify, characterize, prevent or minimize risk**

• **PV** activities and interventions to manage risks
Documentary Requirements

(5) Location Plan

• Sketch of the location
• “how to get there”
• Directions with landmarks
• GPS Coordinates
Documentary Requirements

(6) Site Master File

• Based on PIC/s GMP, following the format provided under Bureau Circular No. 3 s. 2005
Documentary Requirements

(7) Proof of Payment

• OR or payment slip
Documentary Requirements

(8) Self-assessment Toolkit
F. INSPECTION REQUIREMENTS
Inspection Requirements

In addition to the submitted documents during application, the following documents will be verified during inspection:

- QMS
- Quality manual and SOPs
- Contract agreements
- Qualification and Validation Documents
Inspection Requirements

In addition to the submitted documents during application, the following documents will be verified during inspection:

- Master and Batch Production Records
- Specifications
- Reference Materials
- Other procedures, protocols, records, and reports
G. REGISTRATION REQUIREMENTS
MEMO: PSD02-12

September 3, 2002

To: ALL CONCERNED COMPANIES

From: NAZARITA T. LANUZA
OIC, Product Services Division

Subject: UPDATED CHECKLIST OF REQUIREMENTS FOR REGISTRATION
MEMO: PSD02-12

1. Application Form
2. Copy of Valid agreement
3. Valid LTO
4. Flow chart of Manufacturing Procedure, description of Manufacturing Process, Equipment Used, Sampling, and In-Process Controls
5. Technical Specifications of Finished Product
MEMO: PSD02-12

6. Complete Quality Control Procedures
7. Certificate of Analysis of Finished Product
8. Certificate of Analysis issued by CIGI
9. Philippine Standard Quality Certification Mark
10. Labeling Materials
H. FUTURE DIRECTIONS
Specific requirements for licensing of hospitals engaged in the manufacture of medical oxygen

Registration requirements/certification for medical gases in tanks or delivered in tubes
I. DISCUSSION