BFAD REGULATION
No. 1 s. 1988

SUBJECT: AMENDED GENERAL REGULATIONS FOR THE LICENSING OF
DRUG ESTABLISHMENTS

Pursuant to Section 26(a) in relation to Sections 21-a and 11(k) of Republic Act 3720, as
amended by Executive Order No. 175 s. 1987 dated May 22, 1987, the following
guidelines and regulations are hereby promulgated to effectively implement the control
and supervision of drug establishments by the Bureau of Food and Drugs (BFAD).

Section 1. Definition of Terms

For the purpose of this Regulation, the term :

1.1. “Act” means the Foods, Drugs and Devices and Cosmetics Act and all
amendments thereto. (R.A. 3720 as amended)

1.2. “Director” means the Director of the Bureau of Food and Drugs.

1.3. “Drug” means (1) articles recognized in the current official United States
Pharmacopoeia-National Formulary; Official Philippine National Drug
Formulary, or any supplement to any of them; and (2) articles intended
for use in the diagnosis, cure, mitigation, treatment or prevention of
disease in man or other animals; and (3) articles (other than food)
intended to affect the structure or any function of the body of man or
animals; and (4) articles intended for use as a component or any article
specified in clauses (1), (2) or (3) but do not include devices or other
components, parts or accessories.

1.4. Drug Establishments include:

1.4.1. Drug Manufacturer
1.4.2. Drug Producer
1.4.3. Drug Assay Laboratory
1.4.4. Drug Department
1.4.5. Drugstore, Pharmacy or Botica
1.4.6. Retail Outlet for Non-Prescription on Drugs

1.5. “Drug Manufacturers” means an establishment engage in any or all
operations involved in the production of a drug, including propagation,
processing, compounding, finishing, filling, packing, repacking, altering,
ornamenting, finishing and labeling with the end in view of its storage,
sale or distribution; Provided, that the term shall not apply to the
compounding and filling of prescription in drugstores and hospital
pharmacies.

1.6. “Drug Producer” means an establishment which acts like a manufacturer
in initially procuring its own raw materials and packaging components for
the producer’s own products, but then sub-contracts the manufacture to
a BFAD-licensed drug manufacturer, such products are manufactured in
accordance with the producer’s specifications, production monographs
and quality control procedures with the producer maintaining quality control authority and approval for marketing.

1.7. “Drug Assay Laboratory” means an establishment where drug products or chemical substances (synthetic or natural) are analyzed, assayed or identified.

1.8. “Drug Department” means an establishment or part of an establishment where drugs, medicines, pharmaceutical specialties, and chemical-drugs are locally obtained or imported for itself or other drug establishments, exported, stored, promoted or distributed or sold at wholesale only.

1.9. “Drugstore, Pharmacy or Botica” which includes Hospital Pharmacy/Dispensary, means an establishment or part of an establishment where registered drugs, chemical products, active principles, medicinal or galenical preparations, proprietary medicines or pharmaceutical specialties, biological products and poisons are sold and where medical, dental and veterinary preparations are compounded and/or dispensed.

1.10. “Retail Outlet for Non-Prescription Drugs means an establishment or part of a retail establishment where registered non-prescription drug products are sold in their original packages, bottles or containers.

1.11. “Poison” means any drug, chemical, active principle, or preparation of the same, capable of destroying life or seriously endangering health when supplied to the body externally or in moderate dosages internally.

1.12. “Abortive Preparation” means any drug, chemical product, or active ingredient or mixture of preparation of the same, capable of provoking abortion or expulsion of the fetus, in one or several dosages.

1.13. “Prescription Drugs” or “Ethical Drugs” are pharmaceutical products or drug preparation that are to be dispensed with only upon written order of a duly licensed physician, dentist or veterinarian for the management or treatment of a condition or a diagnosed disease.

1.14. “Non-Prescription Drugs” are pharmaceutical products or drug preparations that can be dispensed without the written order of a duly licensed physician, dentist or veterinarian, for the use of consumers for the prevention or symptomatic relief of minor or self-limiting ailments.

1.15. “Proprietary Drugs” means any drug, preparation and mixture of drugs, active principle, chemical product, marketed under a trade/brand name.

Section 2. General Requirements for Licensing of Drug Establishments

2.1. Any person desiring to operate or establish a drug establishment shall file with the Office of BFAD a sworn petition stating, among other :

2.1.1. The name, age, citizenship of the petitioner and other personal circumstances;

2.1.2. The place where it is to be established;

2.1.3. The name of establishment, as duly registered with the Bureau of Domestic Trade (BDT), in case of single proprietorship, or with the Securities and Exchange Commission (SEC), in case of corporation, partnership or other juridical person, together with the Xerox copy of its registration papers with said Agency, as the case maybe as evidenced by Certificate of Registration duly issued by said Office;

2.1.4. That a registered Filipino pharmacist shall be employed; Provided however, that in case of drug stores or hospital pharmacies, the name of pharmacist-in-charge, the number of Certificate of Registration duly issued by the Professional Regulation
Commission (PRC) and its date of issue must be specifically stated;

2.1.5. That the owner/pharmacist has attended a BFAD-sponsored Seminar on Licensing of Drug Establishments;

2.1.6. That the establishment is a member in good standing of a BFAD-accredited drug or pharmaceutical association; Provided, however, that a duly acknowledged application for membership in the Association, for those not yet a regular member, may be considered. Provided, further, that a renewal of license shall be affected by BFAD until full compliance on Association’s membership is made; and

2.1.7. An undertaking to the effect that the petitioner agreed to change the business/corporate/firm name of the establishment in the event that there is a similar name or such name is otherwise misleading.

2.2. No person shall manufacture, sell, offer for sale, import, export, distribute or transfer any drug without first securing a license to operate from the BFA after due compliance with technical requirements in accordance with the guidelines and regulations promulgated by BFAD.

2.3. Any owner, administrator or manager of any drug establishment desiring to transfer to another place shall notify the BFAD stating the place where he intends to move, and shall establish his new place of business, in which case, the necessary petition form shall be duly accomplished, subject to compliance with requirements of this Regulation.

2.4. The License to Operate a drug establishment approved and issued by the Director shall at all time be displayed in a conspicuous place within the establishment.

Section 3. Specific Requirements for Licensing of Drug Establishments

In addition to General Requirements indicated in Section 2 hereof, the specific requirements necessary for the opening of drug establishments shall be in accordance with the following:

3.1. Requirements for a Drug Manufacturing Laboratory

A. Submission of the following documents:
   1. Duly Accomplished Petition Form: (RD Form No. 1)
   2. Xerox copy of Business Name Registration/Registration Certificate issued by the BDT or SEC, as he case maybe;
   3. Location Plan, Buildings and Floor Plans;
   4. List of Products intended for manufacture;
   5. List of Production Equipment indicated in ANNEX “A” hereof;
   6. List of Quality Control Equipment indicated in ANNEX “B” hereof; and
   7. Feasibility Study.

B. Compliance with Requirements enumerated in Nos. 3,4, 5 and 6 of A.1. A, Section 3 of this Regulation.

C. Reference Books:
   1. Official Philippine National Drug Formulary
   2. Official United Stated Pharmacopoeia-National Formulary (USP-NF)
4. Foods, Drugs and Devices and Cosmetic Act (RA 3720, as amended and its implementing rules and regulations); and
5. Pharmacy Law (RA 5921, as amended) and its implementing rules and regulations.

3.2. Requirements for a Drug Producer

A. Submission of the following documents:
1. Duly accomplished Petition Form; (RD Form No. 1)
2. Xerox Copy of Business Name Registration/Registration Certificate issued by BDT or SEC, as the case maybe;
3. List of Products intended for production; and

B. Premises
1. An adequately ventilated office with concrete, tile of wooden flooring;
2. A warehouse suitable for the storage of drugs or chemicals, separate from general merchandise;
3. An air conditioned storage place for biologic products and pharmaceutical specialties, separate from general merchandise.
4. Separate cabinets for keeping poison and dangerous drugs; and
5. Display cabinet for products carried by the Drug producers.

C. Reference Books
1. Official Philippine National Drug Formulary
2. Official United Stated Pharmacopoeia-National Formulary (USP-NF)
4. Foods, Drugs and Devices and Cosmetic Act (RA 3720, as amended and its implementing rules and regulations); and
5. Pharmacy Law (RA 5921, as amended) and its implementing rules and regulations.

D. Record Books Duly Registered with BFAD

3.3. Requirements for a Drug Assay Laboratory

A. Submission of the following documents:
1. Duly accomplished Petition Form; (RD Form No. 1)
2. Xerox Copy of Business Name Registration/Registration Certificate issued by BDT or SEC, as the case maybe;
3. Location Plan, Building and Floor Plan; and
4. List of Quality Control Equipment indicated in Annex “B”

3.4. Requirements of a Drug Department

A. Submission of the following documents:
1. Duly Accomplished Petition Form: (RD Form No. 1)
2. If corporation or partnership Registration Certificate with SEC and Article of Incorporation; If single proprietorship, copy of Business Registration with BDT; and
3. List of Products intended for distribution.
B. Premises
1. An adequately ventilated office with concrete, tile of wooden flooring;
2. A warehouse suitable for the storage of drugs or chemicals, separate from general merchandise;
3. An air conditioned storage place for biologic products and pharmaceutical specialties, separate from general merchandise.
4. Separate cabinets for keeping poison and dangerous drugs
5. Display cabinet for products carried by the Drug Department.

C. Reference Books:
1. Official Philippine National Drug Formulary
2. Official United Stated Pharmacopoeia-National Formulary (USP-NF)
4. Foods, Drugs and Devices and Cosmetic Act (RA 3720, as amended and its implementing rules and regulations); and
5. Pharmacy Law (RA 5921, as amended) and its implementing rules and regulations.

D. Record Books duly registered with BFAD
1. Batch Distribution Record Book.

3.5. Requirements of a Drugstore, Pharmacy or Botica
A. Submission of the following documents:
1. Duly accomplished Petition Form; (RD Form No. 2)
2. Pharmacist’s PRC Registration Certificate, Privilege Tax Receipt (PTR) and one (1) copy of 1x1 ID picture; and
3. (a) If corporation or partnership, copy of Registration Certificate with SEC and Article of Incorporation; and (b) If single proprietorship, copy of Business Name Registration with BDT.

B. Premises
1. A signboard in front of the place of business bearing the name of the drugstore. (Except for Hospital Pharmacy)
2. A well-ventilated area not less than 20 sq. m. in floor area with concrete tile or wooden flooring.
3. A place suitable for compounding medical prescription and for washing and sterilizing bottles (for hospital pharmacies only)
4. A suitable and proper place for the adequate storage of drugs, biological products and medicinal substances.
5. Suitable cabinets for keeping poisons and/or dangerous drugs.

C. Reference Books:
1. Official Philippine National Drug Formulary
2. Official United Stated Pharmacopoeia-National Formulary (USP-NF)
4. Foods, Drugs and Devices and Cosmetic Act (RA 3720, as amended and its implementing rules and regulations); and
5. Pharmacy Law (RA 5921, as amended) and its implementing rules and regulations.
D. Record Books duly registered with BFAD
   1. Prescription Book.
   2. Dangerous Drug Book
   3. Exempt Preparation Book
   4. Poisons and Abortives Book
   5. Record Book for Selected Non-Prescription Drugs, as
determined by BFAD

E. Utensils, Apparatus and Other Equipment
   1. For Hospital Pharmacy only:
      1.1. Balances
          a. Prescription balance of one centigram sensitivity
          b. One set of weights
      1.2. Glass measures a set of not less than six (6) from 45 cc to
           1000 cc
      1.3. Mortar and Pestle – a set of not less than three (3)
           assorted sizes
      1.4. Glass Funnels – a set of not less than three (3) assorted
           sizes
      1.5. Other laboratory apparatus/supplies
   2. For all drugstores including hospital pharmacies
      2.1. Refrigerator – for biological and other drug product
           needing refrigerator

3.6. Requirements for a Retail Outlets for Non-Prescription Drugs
A. Submission of the following documents:
   1. Duly Accomplished Petition Form (RD Form No. 2)
   2. Pharmacist’s PRC Registration Certificate, Privilege Tax Receipt (PTR)
      and one (1) copy of 1 x 1 ID picture; and
   3. (a) If corporation or partnership, a copy of Registration Certificate with
      SEC Article of Incorporation; and (b) If single proprietorship, a copy of
      Business Name Registration with BDT.

B. Premises
   1. A signboard in front of the place of business, bearing the name of the retail
      outlet;
   2. A well-ventilated area with tile or wooden flooring; and
   3. A suitable and proper place for the adequate storage of non-prescription
      drugs.

C. Reference Books :
   1. Official Philippine National Drug Formulary;
   2. Drug Reference Manual;
   3. Foods, Drugs and Devices and Cosmetic Act (RA 3720, as amended and
      its implementing rules and regulations); and
   4. Pharmacy Law (RA 5921, as amended) and its implementing rules and
      regulations.

D. Record Books
   1. Record Books as required by BFAD, for selected non-prescription drugs.

Section 4. Other Requirements

4.1. Unless otherwise provided, every drug establishment shall have in its
      employ, during actual business operation, at least one registered
      pharmacist. The PRC Certificate of Registration of all pharmacist under the
employ of the drug establishment shall be displayed in a conspicuous place within the establishment and this practice shall be limited within the premises thereof.

4.2. Within five (5) days after a pharmacist shall have ceased to be employed or to manage a drug establishment, the owner/manager or administrator thereof shall report the fact to the Director. The name of the new pharmacist; his registration certification, number and date of issue and post-office address shall be subsequently reported.

4.3. In case of inter-laboratory sub-contracting, the written agreement between drug manufacturing laboratories must be immediately reported to BFAD.

Section 5. Schedule of Fees

5.1. For every License to Operate a drug establishment approved and issued by the Director, a fee shall be charge in accordance with the following Schedules:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>DM</td>
<td>Drug Manufacture</td>
<td>P 5,000.00</td>
</tr>
<tr>
<td>DP</td>
<td>Drug Producer</td>
<td>P 3,000.00</td>
</tr>
<tr>
<td>DAL</td>
<td>Drug Assay Lab.</td>
<td>P 4,000.00</td>
</tr>
<tr>
<td>DD</td>
<td>Drug Department</td>
<td>P 2,000.00</td>
</tr>
<tr>
<td>DO</td>
<td>Drugstore, Hospital Pharmacy or other Drug Outlets</td>
<td>P 500.00 per outlet</td>
</tr>
</tbody>
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Section 6. Validity of License

6.1. The initial License to Operate shall be invalid for a period of one (1) year from date of issuance.

6.2. Subsequent renewal shall be valid for a period of two (2) years upon payment of fees and satisfactory showing that the applicant's establishment is a member of a good standing of a BFAD accredited drug or pharmaceutical Association

6.3. A surcharge of fifty (50%) percent of the Schedule Fee shall be impose for late renewal of License to Operate.

Section 7. Sanctions

7.1. For violation of this Regulation, after due notice and hearing, any or all of the following sanctions may be imposed by the Director, upon recommendation of BFAD Legal Division:

7.1.1. Written notice of hearing or reprimand for minor violations;
7.1.2. Suspension or Revocation of License to Operate;
7.1.3. Imposition of Administrative Fines, in an amount not less than P1,000.00 nor more than P5,000.00;
7.1.4. Recommendation for administrative discipline of erring pharmacist, physicians and other persons to appropriate government agencies; and
7.1.5. Institution of appropriate criminal proceeding against persons responsible for violations.

Section 8. Repealing Clause
8.1. All administrative order, rules and regulations and other administrative issuance or parts thereof, inconsistent with the provisions of this Regulation are hereby repealed or modified accordingly.

Section 9. Effectivity

9.1. This regulation shall take effect immediately following publication in a newspaper of general circulation or in the Official Gazette. However, those drug establishments already existing on the date of effectivity of the Regulation are given period of one (1) year within which to comply.

(Sgd) CATALINA C. SANCHEZ
Director

Approved:

(Sgd) ALFREDO R.A. BENZON, M.D.
Secretary of Health