REVISED IMPLEMENTING RULES AND REGULATIONS (IRR) OF REPUBLIC ACT (R.A.) NO. 8203, OTHERWISE KNOWN AS "THE SPECIAL LAW ON COUNTERFEIT DRUGS"

AUTHORITY

Pursuant to the Authority:

a) Of the Office of the Secretary of Health to exercise supervision over the Food and Drug Administration pursuant to Section 5 of Republic Act No. 9711, amending Section 4 of Republic Act No. 3720, as amended;

b) Of the Department of Health under Section 3(9), Chapter 1, Title IX of Executive Order No. 292 or the Administrative Code of 1987, to issue orders and regulations concerning the implementation of established health policies;

c) Of the Bureau of Food and Drugs (now Food and Drug Administration) under Section 15(2), Chapter 4, title IX of Executive Order No. 292, to act as the policy formulation and sector monitoring arm of the Secretary of Health on matters pertaining to food, drugs, traditional medicines, cosmetics and household products containing hazardous substances, and the formulation of rules, regulations and standards in accordance with Republic Act No. 3720 (1963), as amended by Executive Order No. 175 s. 1987, and other pertinent laws for their proper enforcement; and,

d) Under Section 3, Rule VIII, on amendments, of the rules and regulations implementing Republic Act No. 8203 otherwise known as "The Special Law on Counterfeit Drugs", issued pursuant to Section 11 of the Act;

the Secretary of Health hereby promulgates the following Revised Implementing Rules and Regulations.

RULE I. GENERAL PROVISIONS

Section 1. *Short Title.* These rules shall be referred to as the *"Revised Implementing Rules and Regulation of Republic Act No. 8203, or the Special Law on Counterfeit Drugs".*

Section 2. *Declaration of Policy.* It is hereby the policy of the State to protect and promote the right to health of the people and instill health consciousness among them as provided in Section 15 Article II of the Constitution.

It is also further declared the policy of the State that in order to safeguard the health of the people, the State shall provide for their protection against counterfeit drugs.

Section 3. *Construction.* The words and phrases used in this Revised Rules and Regulations shall be interpreted and implemented consistent with the above declared policy.

RULE II. DEFINITION OF TERMS

Section 1. *Definition of Terms.* As used in these revised rules, the term:

a) *"Act"* shall refer to Republic Act No. 8203 or the "The Special Law on Counterfeit Drugs".

b) *"Brokering"* shall refer to any act of facilitating the disposal or sale of counterfeit drugs, including acts of agency.

c) *"CDRR"* shall refer to the Center for Drug Regulation and Research of the FDA.

d) *"Constructive Knowledge"* as herein applied shall mean, that by exercise of [illegible] care and would have known the fact or suspect that the

b) Possession of any such counterfeit drugs. However, any person found in possession of counterfeit drugs, in violation of this subsection, shall be excepted from liability under the provisions of the Act after:

1) Presentation of sales invoices, official receipt or other legally acceptable documents evidencing his purchase thereof from a drugstore, distributor, manufacturer, hospital pharmacy or dispensary; or any other person or place duly licensed to sell and/or dispense drugs or medicines, and indicating therein the batch and lot numbers, as well as the expiry dates of such drugs; or

2) Presentation of certificates and other documents evidencing the importation or exportation of the counterfeit drugs found in his possession as required by existing laws, including those documents required in the preceding paragraph covering the commercial transactions involving counterfeit drugs;

In both cases, the subject counterfeit drugs must not on their face appear to be as such, or do not bear any marking or any patently unusual characteristic sufficient to arouse the suspicion of a reasonable and prudent person that such drugs are counterfeit. Furthermore, the amount or volume of counterfeit drugs held is such that it does not negate or is inconsistent with the averment that the same are for personal use, notwithstanding the presentation by the possessor of medical records and other similar documents accompanying and justifying the use of such drugs;

c) Forging, counterfeiting, simulating or falsely representing, or without proper authority, using any mark, stamp, tag, label or other identification mark or device authorized or required by Republic Act No. 3720, as amended, and/ or the regulations promulgated under the Act;

d) Photocopying, duplicating, altering, printing, transferring, obliterating or removing the approved label or any part thereof, lawfully belonging to another person, for the purpose of using such label or a part thereof on any counterfeit drug: *Provided,* that if the person who committed any of the acts enumerated in this paragraph and the person who used the labels produced thereby are not one and the same person and the former had knowledge of the purpose for which the labels are intended, the former shall also be liable under the Act notwithstanding the failure of the latter to achieve the intended purpose; and

e) Making, selling, or concealing any punch, dye, plate or any other equipment or instrument designed to print, imprint or reproduce the trademark, trade name or other identifying mark of another registered producer or any likeness thereof, upon any drug product or device or its container or label without authority from the legitimate owners of the trademark or trade name.

RULE IV. PARTIES LIABLE

Section 1. *Parties Liable.* The following persons shall be liable for violation(s) of the Act:

a) the manufacturer, exporter or importer of the counterfeit drugs and their agents: *Provided,* that the agents shall be liable only upon proof of actual or constructive knowledge that the drugs are counterfeit;

b) the seller, distributor, trafficker, broker or donor and their agents, upon proof of actual or constructive knowledge that the drugs sold, distributed, offered or donated are counterfeit drugs;

c) the possessor of counterfeit drugs as provided in Section 4(b) of the Act or Rule III, Section 1 (b) hereof;

d) the manager, operator or lessee of the laboratory or laboratory facilities used in the manufacture of counterfeit drugs;

e) the owner, proprietor, administrator or manager of the drugstore, hospital pharmacy or dispensary, laboratory or other outlets or premises where the counterfeit drug is found who induces, causes or allows the commission of any act herein prohibited;

medicine to the FDA within ten (10) days from the time of purchase or acquisition of such drugs as indicated in the sales invoices or official receipts or other similar documents. The sales invoice, official receipts or other similar documents shall be attached to the said report on counterfeit drug/medicine. The FDA shall proceed with the verification/investigation against the establishment from where the counterfeit drug/medicine was purchased or acquired following the procedure in the preceding section.

Failure of the owners of trademarks, trade names or other identifying marks, or their authorized agents to comply with this section will give rise to the *prima facie* evidence of violation as provided under Section 4(a) and Section 1(a) of Rule III. Administrative proceedings may proceed accordingly following Rule VI.

Section 8. *Preventive Closure Order.* A summons with preventive closure order shall be issued against the warehouse, building, factory, store, shop or any other structure where the said counterfeit drugs/medicines are contained or stored within fifteen (15) days upon the filing of administrative complaint pursuant to Section 5 or Section 6 of this rule.

This is for the purpose of preventing the disposition or tampering of evidence, the continuance of acts being complained of, and/or the flight of the Respondent.

After the lapse of the 30-day period, the preventive closure order is deemed lifted without prejudice to the resolution of the case.

The administrative proceedings shall proceed in accordance with Rule VI.

RULE VI. PROCEDURE IN THE FILING OF ADMINISTRATIVE COMPLAINT

GENERAL PROVISIONS.

Section 1. *Interpretation.* In case of doubt, provisions under this Rule shall be liberally construed to carry out the objectives of promoting the just speedy and inexpensive resolution of cases covered by the Act and these rules and regulations.

Section 2. *Rules of Evidence.* The technical rules of evidence prevailing in the courts of law shall not be strictly applied hereto.

Section 3. *Suppletory Application of the Rules of Court and of the Administrative Code.* In the absence of any applicable provision in this rule, the pertinent provisions of the Administrative Code, Executive Order No. 26, series of 1992, and the Rules of Court, shall suppletorily apply.

VENUE OF ACTIONS

Section 1. *Venue of Actions.* Actions shall be filed, at the option of the complainant or petitioner, with the FDA Central Office or at the FDA Regional Office:

a) Where the establishment complained of is located;

b) Where the product was purchased;

c) Where the product was manufactured; or

d) Where the complainant or petitioner resides.

PARTIES

Section 1. *Who May Be Parties.* Natural or juridical persons may be parties. The party initiating the action shall be called "Complainant/Petitioner" and the opposing party, the "Respondent".

Section 2. *Actions Against Entity Without Juridical Personality.* When two or more persons associated in any business, transact such business under a common name, whether it comprises names of such persons or not, the association may be sued under such common name.

COMMENCEMENT OF ACTIONS

Section 1. *Action; How Commenced.* An action is commenced:

a) upon the filing of a verified complaint or petition by a party; or

b) upon the initiative of the FDA pursuant to its own administrative investigation.

Referral by other government office or officers, or other person shall, upon appropriate verification/investigation, be treated as FDA-initiated action.

Section 2. *Fees and Other Charges.* Appropriate fees and other charges may be

policy.

RULE II. DEFINITION OF TERMS

Section 1. ***Definition of Terms.*** As used in these revised rules, the term:

a) *"Act"* shall refer to Republic Act No. 8203 or the "The Special Law on Counterfeit Drugs".

b) *"Brokering"* shall refer to any act of facilitating the disposal or sale of counterfeit drugs, including acts of agency.

c) *"CDRR"* shall refer to the Center for Drug Regulation and Research of the FDA.

d) *"Constructive Knowledge"* as herein applied shall mean, that by exercise of reasonable care, one would have known the fact or suspect that the drug product — manufactured, exported, imported, sold, offered for sale, distributed, donated, brokered, trafficked, or possessed is counterfeit, such as but not limited to the knowledge, that the drug was not covered by any sales invoice or evidence of delivery or purchase from a FDA-licensed drug establishment.

e) *"Counterfeit Drug/Medicine"* refers to a drug/medicine which does not contain the amounts as claimed; with wrong ingredients; without active ingredients; or with insufficient quantity of active ingredients, which result in the reduction of the product's safety, efficacy, quality, strength or purity. This also refers to a drug/medicine that is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products, including the following:

1) the drug/medicine itself or the container or labeling thereof or any part of such product, container or labeling bearing without authorization the trademark, trade name or other identification marks or imprints or any likeness to that which is owned or registered in the Intellectual Property Office (IPO) in the name of another natural or juridical person;

2) A drug/medicine refilled in containers bearing legitimate labels or marks, without authority; and

3) A drug/medicine which contains no amount of or a different active ingredient; or less than eighty percent (80%) of the active ingredient it purports to possess, as distinguished from an adulterated drug including reduction or loss of efficacy due to expiration.

f) *"Department"* shall refer to the Department of Health.

g) *"Drug"* shall refer to a pharmaceutical product that pertains to chemical compounds or biological substances, other than food, intended for use in the treatment, prevention or diagnosis of disease in humans or animals, including the following:

1) Any article recognized in the official United States Pharmacopoeia/ National Formulary (USP-NF), Homeopathic Pharmacopoeia of the United States of America, Philippine Pharmacopoeia, Philippine National Drug Formulary, British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, and any official compendium or any supplement to them;

2) Any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease of man or animals;

3) Any article, other than food, intended to affect the structure or any function of the human body or animals;

4) Any article intended for use as a component of articles specified in clauses (1), (2), and (3), not including devices or their components, parts, accessories; and

5) Herbal or traditional drugs as defined in R.A. 9502, known as the "Universally Accessible, Cheaper and Quality Medicines Act".

h) *"Establishment"* refer to a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of drug/medicine, including the facilities and installations needed for its activities.

i) *"FDA"* shall refer to the Food and Drug Administration.

j) *"FDRO"* shall refer to the Food and Drug Regulation Officer of the FDA.

k) *"Lifesaving Drugs"* shall refer to drug products indicated for life threatening condition(s).

l) *"LSD"* shall refer to all the laboratories under the FDA.

m) *"LSSC"* shall refer to the Legal Services Support Center of the FDA.

b) the seller, distributor, trafficker, broker or donor and their agents, upon proof of actual or constructive knowledge that the drugs sold, distributed, offered or donated are counterfeit drugs;

c) the possessor of counterfeit drugs as provided in Section 4(b) of the Act or Rule III, Section 1 (b) hereof;

d) the manager, operator or lessee of the laboratory or laboratory facilities used in the manufacture of counterfeit drugs;

e) the owner, proprietor, administrator or manager of the drugstore, hospital pharmacy or dispensary, laboratory or other outlets or premises where the counterfeit drug is found who induces, causes or allows the commission of any act herein prohibited;

f) the registered pharmacist of the outlet where the counterfeit drug is sold or found, who sells or dispenses such drug to a third party and who has actual or constructive knowledge that said drug is counterfeit; and

g) should the offense be committed by a juridical person the president, general manager, the managing partner, chief operating officer or the person who directly induces, causes or knowingly allows the commission of the offense shall be penalized.

RULE V. ADMINISTRATIVE PROCEEDINGS

The FDA is hereby further authorized to undertake the following administrative actions.

Section 1. ***Procedure When Counterfeit Drugs Is Monitored In The Market Pursuant To A Routine Inspection Of The Food And Drug Regulation Officer(s) (FDROs)***

a) If the FDROs, in the course of their routine/regular inspection of a factory, warehouse, establishment in which drugs are manufactured, processed, packed, or held, for introduction into domestic commerce, or vehicle, and all pertinent equipment, finished or unfinished materials, containers, and labeling therein, upon the authority conferred by Section 27 of R.A. No. 3720 as amended, shall suspect certain stocks as counterfeit drug/medicine, the FDRO shall conduct an inventory, segregate and seal the suspected stocks, and collect samples for examination as to the drug product's genuineness and authenticity;

b) The FDRO shall require the owner or the representative of the inspected factory, warehouse, establishment, or vehicle to produce the sales invoice, delivery receipts or documents covering the suspected counterfeit drug/ medicine;

c) The FDRO shall only acknowledge and recognize invoices or documents that have been issued by an FDA-licensed manufacturer, trader, distributor, importer or wholesaler with the name, lot number and expiry date of the drug product(s) indicated therein;

d) Immediately upon return to his/her office, the FDRO concerned shall submit the samples to either the LSD or CDRR or both for their examination or evaluation. The examination or evaluation shall be for the purpose of determining the authenticity and/or genuineness of the said samples;

The CDRR may also require the registered brand-owner of the suspected counterfeit drug to certify whether or not the suspected drug product has been manufactured, imported and/or distributed by them; or whether they own the lot number and expiry date of the same suspected drug product. The certification issued by the registered brand-owner shall be supported by the batch, production and distribution records. However, the brand-owner's certification shall be validated by the CDRR for evidentiary purposes.

Section 2. ***Duration In The Conduct Of Examination.*** The LSD and CDRR shall have twenty (20) working days from receipt to determine the genuineness and authenticity of the product.

Section 3. ***When There Is No Need For Laboratory Testing.*** When the genuineness of the product can be determined by the mere physical examination of the product or the labeling thereof, the CDRR shall conduct the examination or evaluation of the same. The result of the physical examination shall be reduced into a certification of findings.

Section 4. ***When The Product Is Found Not Counterfeit.*** When the result of the examination reveals that the sample collected is genuine, the CDRR or LSD shall forward immediately the report of examination or evaluation to the concerned FDRO through his/her Director.

If the sealed and segregated products are within the Metro Manila Area, the FDRO concerned shall, within two (2) working days from receipt of such report, unseal the sealed and segregated suspected drug product before it can be released for sale or

Section 2. ***Actions Against Entity Without Juridical Personality.*** When two or more persons associated in any business, transact such business under a common name, whether it comprises names of such persons or not, the association may be sued under such common name.

COMMENCEMENT OF ACTIONS

Section 1. ***Action; How Commenced.*** An action is commenced:

a) upon the filing of a verified complaint or petition by a party; or

b) upon the initiative of the FDA pursuant to its own administrative investigation.

Referral by other government office or officers, or other person shall, upon appropriate verification/investigation, be treated as FDA-initiated action.

Section 2. ***Fees and Other Charges.*** Appropriate fees and other charges may be imposed pursuant to the schedule of fees promulgated by the FDA.

Section 3. ***Complaint or Petition by a Party.*** The complaint or petition shall indicate the full name and addresses of the parties and shall set forth in concise manner, the

a) name of the product, the lot numbers and expiry date of the product alleged as counterfeit;

b) specific acts alleged as having been committed by the party-respondent;

c) remedy, relief or action intended for FDA to take; and

d) date of the pleading.

The complaint or petition shall be accompanied by sample(s) of the counterfeit drug/ medicine duly marked for identification purposes.

The complaint or petition must be signed by the party or counsel representing him/her, stating in either case his/her address which should not be a post office box.

The complaint or petition must likewise be supported by an affidavit that the affiant has read the pleading and that the allegation therein are true and correct of his/her personal knowledge or based on authentic documents.

The complaint or petition shall contain a sworn certification:

a) that he/she has not theretofore commenced any action or filed any claim involving the same issues in any court, tribunal or quasi-judicial agency and to the best of his/her knowledge, no such similar action or claim is pending therein;

b) if there is such other pending action or claim, a complete statement of the present status thereof; and

c) if he/she should hereafter learn that the same or similar action or claim has been filed or is pending, he/she shall report that fact within five (5) days therefrom.

Section 4. ***Actions Initiated by FDA.*** For actions initiated by the FDA, the FDRO or any authorized official or personnel of the FDA investigating the case, the report of violation shall constitute as the complaint.

The report of violation shall clearly state the acts or omissions in violation of the law, rules and regulation, the party or person who committed the violation shall be accompanied by the record of inspection and if applicable, the report of analysis/ verification with respect to the product(s).

The record of inspection shall indicate:

a) The time and date of inspection;

b) The FDA license number of the establishment inspected, and the validity of such license to operate, if any;

c) The name and place or exact address of the establishment and the person who committed the violation;

d) The manner of the collection of samples, if any;

e) The inventory of the product from where the sample is taken; and

f) The findings of inspection and other relevant facts.

Section 5. ***Cases Referred by the Government Office or Officer or other Person.*** Cases referred by the government office or officer shall undergo FDA verification/ investigation and shall proceed in accordance with Section 6 of Rule V.

Section 6. ***Anonymous Complaints/Petitions; Requests for Confidentiality.*** Anonymous complaints and complaints/petitions by parties requesting confidentiality of their identities shall undergo the FDA verification/investigation and shall likewise proceed in accordance with Section 6 of Rule V.

SERVICE OF PLEADINGS AND OTHER PARTIES.

Section 1. ***Filing and Service of Pleadings.*** All pleadings and other papers in connection with the case shall be filed with the docketing unit in the FDA central office

use, testing, promotion, advertising, or sponsorship of drug/medicine, including the facilities and installations needed for its activities.

i) *"FDA"* shall refer to the Food and Drug Administration.

j) *"FDRO"* shall refer to the Food and Drug Regulation Officer of the FDA.

k) *"Lifesaving Drugs"* shall refer to drug products indicated for life threatening condition(s).

l) *"LSD"* shall refer to all the laboratories under the FDA.

m) *"LSSC"* shall refer to the Legal Services Support Center of the FDA.

n) *"Online Service"* shall refer to the sale, offering for sale, donation, distribution, trafficking, brokering of drug/medicine, or the sale of any punch, dye, plate or any other equipment or instrument designed to print, imprint or reproduce the trademark, trade name or other identifying mark for use to any drug product, through and with the use of information and communication technology system. The term shall also cover Online Selling or Online Pharmacy.

o) *"Owner"* shall refer to a person or group of persons who is the registered owner of a license to operate a business or business undertaking in the Philippines or the branch manager or operator, licensee, franchisee, or any person acting on behalf of the corporate entity.

p) *"Pharmaceutical Products"* shall refer to drugs, medicines, biologicals, pharmaceutical and biopharmaceutical products/specialties, veterinary products, veterinary biologics and veterinary medicinal products.

q) *"REU"* shall refer to the Regulatory Enforcement Unit of the FDA.

r) *"Residence"* shall refer to a private dwelling or abode where a person lives, either as owner or lessee, or usufructuary including, for purposes of this Act, its yard, garage, storage rooms or premises, provided that where the yard, garage, storage rooms or premises are used to manufacture, process, pack, or hold drugs/medicine for introduction into domestic commerce, the same shall not fall as residence but be considered as establishment.

RULE III. PROHIBITED ACTS.

Section 1. ***Prohibited Acts.*** The following acts are declared unlawful and therefore prohibited:

a) The manufacture, sale, offering for sale, donation, distribution, trafficking, brokering, exportation, or importation or possession of counterfeit drugs as defined in Section 3 hereof not otherwise covered by Republic Act No. 3720, as amended. The presence or availability of such counterfeit drugs within the premises of any entity engaged in the sale, manufacture or distribution of drugs and/or pharmaceutical products or in a private residence, or in public or private vehicle, or in the premises not covered by a valid license to operate from the FDA, shall constitute a *prima facie* evidence of violation of the Act: *Provided, however,* that this presumption shall not apply to the legitimate owners of trademarks, trade names or other identifying marks, or the legitimate or authorized representatives or agents of such owners, who have in their possession counterfeit drugs which bear the trademarks, trade names or marks if they can show the sales invoices or official receipts evidencing their purchase from a drugstore, manufacturer or distributor suspected by them of dealing in counterfeit drugs involving the trademarks, trade names and other similar identifying marks registered in their names: *Provided, further,* That such counterfeit products shall be reported and immediately turned over to the FDA: *Provided, finally,* That compliance with the preceding *proviso* shall be made within a period of ten (10) days from the date of purchase of such counterfeit drugs as indicated in the sales invoice, official receipt, or other similar documents abovementioned to the time the counterfeit drugs are reported and turned over to the FDA;

the labeling thereof, the CDRR shall conduct the examination or evaluation of the same. The result of the physical examination shall be reduced into a certification of findings.

Section 4. ***When The Product Is Found Not Counterfeit.*** When the result of the examination reveals that the sample collected is genuine, the CDRR or LSD shall forward immediately the report of examination or evaluation to the concerned FDRO through his/her Director.

If the sealed and segregated products are within the Metro Manila Area, the FDRO concerned shall, within two (2) working days from receipt of such report, unseal the sealed and segregated suspected drug product before it can be released for sale or distribution to legitimate commerce.

When the segregated and sealed products are located outside the Metro Manila area, the FDRO concerned shall, within three (3) working days from receipt of the notice, unseal such sealed and segregated suspected drug products before it can be released for sale or distribution to legitimate commerce.

Section 5. ***When The Product Is Found Counterfeit.*** When the result of examination shall confirm the suspicion of the FDRO that in fact the drug product is counterfeit, the LSD or CDRR shall forward the result of examination to the concerned FDRO, through his/her Director, for the filing of administrative complaint under Rule VI hereof.

Section 6. ***Procedure When Information About The Presence Of Counterfeit Drug/Medicine In The Possession Of Any Person Or Establishment Is Received.***

a) Any information, either referred by the government office or officer or from anonymous sources or person requesting confidentiality of their identities, on the existence of suspected counterfeit drug/medicine in the possession of any manufacturer, seller or distributor, shall undergo the verification process by the FDRO, or any officer deputized or authorized by the Director General of the FDA. Verification process shall follow the existing system and procedure in the conduct of case build-up, investigation and other appropriate intervention adopted by the FDA. Verification process shall include a determination whether or not the subject establishment is covered by a license to operate issued by FDA or in a private residence.

b) If verification process confirms that counterfeit drug/medicine indeed exists the FDRO, or any officer deputized or authorized by the Director General of the FDA, shall:

1. If the establishment is duly licensed by the FDA:
   i. Segregate, inventory and seal such counterfeit drugs;
   ii. Obtain a valid search warrant from a competent court;
   iii. After having obtained the search warrant, seize such counterfeit drugs and take them into custody;
   iv. Proceed in filing a criminal complaint and administrative complaint.
2. If private residence or in other premises not covered by a valid license to operate:
   i. Secure a valid search warrant from a competent court;
   ii. After having obtained the search warrant, inventory and seize such counterfeit drugs and take them into custody;
   iii. Proceed in filing a criminal complaint and administrative complaint.

Section 7. ***Possession of Counterfeit Drug/Medicine by Owners of Trademarks, Trade Names or Other Identifying Marks; When to report.*** Owners of trademarks, trade names or other identifying marks, or their authorized agents who have in their possession counterfeit drug/medicine involving their own trademark, trade name or other identifying marks shall report in writing and turn over the said counterfeit drug/

Cases referred by the government office or officer shall undergo FDA verification/ investigation and shall proceed in accordance with Section 6 of Rule V.

Section 6. ***Anonymous Complaints/Petitions; Requests for Confidentiality.*** Anonymous complaints and complaints/petitions by parties requesting confidentiality of their identities shall undergo the FDA verification/investigation and shall likewise proceed in accordance with Section 6 of Rule V.

SERVICE OF PLEADINGS AND OTHER PARTIES.

Section 1. ***Filing and Service of Pleadings.*** All pleadings and other papers in connection with the case shall be filed with the docketing unit in the FDA central office or appropriate regional office.

Section 2. ***Service of Summons, Notices, Decisions and Orders.***

a) Summons, notices, and copies of decisions and orders shall be served on the parties to the case personally by the duly authorized process server or other authorized officer of the FDA, or by registered mail, and such other acceptable modes of service.

b) The serving officer shall submit his return within three (3) days from date of service thereof, stating legibly in his return his name, the name of person served, and the date of receipt, which return shall be immediately attached to and shall form part of the records of the case. If no service was effected, the serving officer shall state the reason therefore in his return.

PLEADINGS OR MOTIONS

Section 1. ***Prohibited Pleadings or Motions.*** The following pleadings and motions shall be prohibited:

a) Motion to dismiss, except a motion to dismiss based on lack of jurisdiction;

b) Motion for extension of time to file answer, affidavit, position paper and other pleadings;

c) Counterclaim or Cross-Claim;

d) Third party complaint;

e) Motion to Intervene;

f) Dilatory Motion for Postponement;

g) Motion for Bill of Particulars;

h) Reply;

i) Motion for Reconsideration of interlocutory orders or interim relief orders;

j) Second Motion for Reconsideration

PROCEEDINGS BEFORE THE FDA

Section 1. ***Docketing of Cases.*** All complaints, petitions, formal charges and referrals shall be properly received and docketed at the FDA Central Office or at the FDA Regional Office.

Section 2. ***Summons.*** From the issuance of the summons with preventive closure order, the same shall be served to the respondent within five (5) days attaching thereto the complaint/petition and the supporting documents, and requiring him/her to file his/her answer within a non-extendible period of ten (10) days from receipt of the summons.

Section 3. ***Temporary and/or Preventive Measure Order.*** The FDA for the purpose of preventing the disposition or tampering of evidence, the continuance of acts complained of, and the flight of the Respondent, as the case may be, may order any or all of the following:

a) The seizure of the counterfeit drug product subject of the complaint or action for cases falling under Section 1 of Rule V.

b) The preventive closure for a period of not exceeding thirty (30) days of the warehouse, building, factory, store, shop, or any other structure where the said counterfeit drug products are contained or stored. After the lapse of the 30-day period, the preventive closure order is deemed lifted without prejudice to the resolution of the case.

c) The withholding of such health products from being transported or transferred.

d) The seizure of paraphernalia, machines, vehicles and the like believed to have been used in the commission of the offense.

PRELIMINARY CONFERENCE

Section 1. ***Preliminary Conference/Clarificatory Hearing.*** Except on *motu propio* cases, the FDA may, upon motion of any party schedule the Preliminary Conference, which shall not be later than fifteen (15) days from the receipt of the Answer, to consider the following issues:

a) The simplification of the issues;

b) The necessity or desirability of amendments to the pleadings;

c) The possibility of obtaining stipulations or admissions of facts and of documents;

d) Such other matters as may aid in the prompt disposition of the case.

When deemed appropriate by the FDA or upon motion by either party, clarificatory hearing may be held during the Preliminary Conference.

SUBPOENA

Section 1. ***Subpoena Duces Tecum and Ad Testificandum.*** The FDA may issue subpoena *duces tecum* and subpoena *ad testificandum*, requiring the production of such books, contracts, correspondence, records, statement of accounts and other documents and/or the attendance or testimony of parties and witnesses as may be material to the investigation of the case.

POSITION PAPER

Section 1. ***Submission of Position Paper and Supporting Evidence.***

a) In cases where a preliminary conference/clarificatory hearing is conducted, within fifteen (15) days from the termination thereof, the parties shall simultaneously submit their respective position paper with supporting affidavits and other documentary evidence.

b) In *motu proprio* cases, the respondent shall submit his/her position paper with supporting affidavits and other documentary evidence within fifteen (15) days from receipt of the summons.

c) The supporting affidavits shall take the place of direct testimony. Affidavits and supporting documentary evidence which were annexed to the complaint or formal charge, and the answer, as the case may be, and forming part of the records of the case, are deemed automatically reproduced for purposes of presentation of evidence and need not be annexed to the position papers. They shall, however, be distinctly identified for reference in the position paper.

DECISION AND ADMINISTRATIVE PENALTIES/SANCTIONS

Section 1. ***When a Case is Submitted for Decision.*** The case shall be deemed submitted for decision from the time of receipt of the filed last pleading, brief or memorandum as may be required by this rule or the expiration of the period for its filing.

Section 2. ***Decision of the FDA.*** The FDA shall issue a decision in writing within thirty (30) days once the case is submitted for decision, which shall contain the following:

a) the relevant facts of the case;

b) the issue/s involved;

c) applicable law and/or jurisprudence;

d) conclusions and reasons therefor; and

e) the appropriate imposable penalty/ies, if warranted

FINALITY OF DECISIONS/ APPEAL

Provided, that should the counterfeit drug/medicine be the proximate cause of death or permanent disability of the victim or patient, permanent disqualification of the person concerned from owning or operating an establishment engaged in any business activity under the supervision of the FDA shall be imposed together with the maximum administrative penalty.

Any of the imposable penalties in Sections 1, 2 and 3 above shall be accompanied by forfeiture, confiscation and destruction of the drug product(s) found to be counterfeit and the equipment, instrument and other articles used in violation of the Act or this implementing rules and regulations.

Section 4. ***When the Minimum Penalty Shall be Applied.*** The minimum administrative penalty shall be imposed when:

a) the counterfeit drug/ medicine subject of the case is not life-saving drugs and the volume of the said products is not worth more than One hundred thousand pesos (PHP100,000.00); or

b) the number of counterfeit drug/medicine subject of the case is not more than three brands or generic products.

Section 5. ***When the Medium Penalty Shall be Imposed.*** The medium administrative penalty shall be imposed when:

a) the counterfeit drug/medicine subject of the case are not life-saving drugs and the volume of the said products is worth more than One hundred thousand pesos (PHP100,000.00) but not exceeding One million pesos (PHP1,000,000.00); or

b) the number of counterfeit drug products is more than three brands or generic products.

Section 6. ***When the Maximum Penalty Shall be Imposed.*** The maximum administrative penalty shall be imposed when:

a) the counterfeit drug/medicine is life-saving regardless of the volume;

b) the volume of the counterfeit drug/medicine is worth more than One million pesos (PHP1,000,000.00); or

c) in case of the aggravating circumstance in Section 2 above.

Section 7. ***Proceedings Against the Registration of a Pharmacist.*** If the offense shall be committed with the actual or constructive knowledge of the registered pharmacist, the administrative sanction that shall be imposed shall be accompanied by the filing of a complaint for the appropriate proceeding against said pharmacist with the Professional Regulation Commission to cancel her/his professional license pursuant to R.A. No. 10918 or the Philippine Pharmacy Act and its Implementing Rules and Regulations.

Section 8. ***When to File Criminal Charges.*** Criminal charges shall be filed against the party liable when the evidence found by FDA is considered sufficient to establish a probable cause.

RULE VIII. CRIMINAL SANCTIONS

Section 1. ***Criminal Sanctions.*** The commission of any of the acts prohibited under Section 4 of the Act or Rule III hereof shall be punished by:

a) imprisonment of not less than six (6) months and one (1) day, but not more than six (6) years for mere possession of counterfeit drugs as provided for in Section 4 (b) of the Act; or

b) imprisonment of six (6) years and one (1) day, but not more than ten (10) years or a fine of not less than One hundred thousand pesos (PHP100,000.00) but not more than Five hundred thousand pesos (PHP500,000.00) or both such imprisonment and fine at the discretion of the court in any other case mentioned in Section 4 of the Act; or

c) imprisonment of not less than six (6) months and one (1) day, but not more than two (2) years and four (4) months if the counterfeit drug is intended for animals; or

d) imprisonment of not less than six (6) years and one (1) day but not more than ten (10) years for any manufacturer, seller or distributor who shall conceal, substitute, dispose or destroy any drug as may have been segregated and sealed by the FDA, or who shall break, alter or tamper any mark or seal used by the FDA to identify those segregated drugs as provided for under

Suicide bomber attacks Indonesian police station; 6 hurt

EDAN (AP) — A suicide bomber blew himself up at a busy police station in Indonesia's third largest city yesterday, injuring at least six people, during a counterterrorism crackdown and a warning about possible attacks against police and houses of worship.

The attacker got past a guard post and into the yard of the Medan city police station, which was packed with people who were lining up to get various police certificates, said National Police spokesman Muhammad Iqbal.

Iqbal said the attacker detonated his explosives and died near a parking lot after being confronted by other officers, injuring at least four police and two civilians. They were rushed to a nearby police hospital, most with minor injuries.

Television footage showed people running out of the police station and black smoke billowing from a burnt car. Witnesses said the mangled body of the attacker was taken for further identification as an anti-bomb squad secured the location.

Another police spokesman, Dedi Prasetyo, said security procedures had been in place for accepting visitors to the police station, but the attacker ignored police when they tried to check his backpack and tried to reach a nearby canteen inside the station complex when his explosive blasted up to 164 feet from the post.

Prasetyo said that police were still investigating the attack, which came as Indonesia's counterterrorism force worked to root out suspected Islamic militants following last month's assault by a knife-wielding militant couple who wounded Indonesia's top security minister.

More than 40 suspects have been detained by the counterterrorism squad, known as Densus 88, in several provinces, including ones captured on Tuesday, Prasetyo said. The sweep followed a tipoff about possible attacks against police and places of worship in several areas.

Indonesia, the world's most populous Muslim nation, has been battling militants since bombings on the resort island of Bali in 2002 killed 202 people, mostly foreign tourists.

Section 2. *Decision of the FDA.* The FDA shall issue a decision in writing within thirty (30) days once the case is submitted for decision, which shall contain the following:

a) the relevant facts of the case;
b) the issue/s involved;
c) applicable law and/or jurisprudence;
d) conclusions and reasons therefor; and
e) the appropriate imposable penalty/ies, if warranted

FINALITY OF DECISIONS/ APPEAL

Section 1. *Finality of Decision.* The orders, rulings or decisions of the FDA shall become final and executory fifteen (15) days after the receipt of a copy thereof by the party adversely affected, unless the FDA finds that public health requires the immediate execution thereof.

Section 2. *Motion for Reconsideration and Appeal.* Within fifteen (15) calendar days from receipt of the decision the adverse party may file a motion for reconsideration with the FDA, or in case of an adverse decision on the motion for reconsideration, an appeal with the Secretary of Health.

Section 3. *Motion for Reconsideration.* The motion for reconsideration shall be in writing and based only on the findings or conclusions of decision:

a) which are not supported by substantial evidence; or
b) where the conduct of administrative proceeding is attended with irregularity.

Only one (1) motion for reconsideration shall be filed, which shall suspend the running of the period for filing the appeal. However, a Pro-Forma Motion for Reconsideration shall not suspend the period for filing an appeal.

Section 4. *Appeal.* The appeal shall be taken by filing a notice of appeal with the FDA. The FDA shall forward the records of the case to the Office of the Secretary within fifteen (15) days from receipt of the notice of appeal.

Appeal shall be given due course only on the following grounds:

a) abuse of discretion; or
b) decision on the Motion for Reconsideration is not supported by substantial evidence

Section 5. *Appeal Does Not Stay Execution.* An appeal does not stay the decision appealed from unless an order from the Secretary of Health is issued to stay the execution thereof upon proof of posting of the appeal bond equal to the total fine imposed or if none, the amount of One hundred thousand pesos (PHP100,000.00).

EXECUTION OF DECISIONS

Section 1. *Execution.* (a) As soon as a decision becomes final and executory, either upon motion of the interested party or *motu proprio*, the FDA, or in instances of appealed cases, the Secretary, shall direct the FDA to issue an order of execution with the corresponding writ of execution directing the Regulatory Enforcement Unit of the FDA to execute said decision. No deputation is necessary.

b) Members of the Philippine National Police (PNP), National Bureau of Investigation (NBI), or any law enforcement agency shall, if requested, render assistance for the effective execution of the orders, rulings or decisions of the FDA.

RULE VII. ADMINISTRATIVE SANCTIONS AND OTHER REMEDIES

Upon finding that the drug/medicine examined are counterfeit and the determination of the parties liable thereof, the FDA shall impose the following:

Section 1. *Minimum Penalty.* An administrative fine of not less than One hundred thousand pesos (PHP100,000.00) but not more than Five hundred thousand pesos (PHP500,000.00) shall be the minimum administrative penalty.

Section 2. *Medium Penalty.* An administrative fine of at least Three hundred thousand pesos (PHP300,000.00) but less than Five hundred thousand pesos (PHP500,000.00) and permanent closure of establishment as well as the revocation of its license to do business shall be the medium administrative penalty.

Provided, that if the Respondent or any of his officer or agent shall conceal, substitute, dispose or destroy any drug/medicine as may have been segregated and sealed by the FDA or who shall break, alter or tamper any mark or seal used by the FDA to identify those segregated drugs; or as a result of the use of the drug/medicine found to be counterfeit, the illness sought to be cured is aggravated or physical injury or suffering results therefrom, the maximum imposable fine of Five hundred thousand pesos (PHP500,000.00) and permanent closure of establishment as well as the revocation of its license to do business shall be imposed.

(PHP500,000.00) or both such imprisonment and fine at the discretion of the court in any other case mentioned in Section 4 of the Act; or

c) Imprisonment of not less than six (6) months and one (1) day, but not more than two (2) years and four (4) months if the counterfeit drug is intended for animals; or

d) imprisonment of not less than six (6) years and one (1) day but not more than ten (10) years for any manufacturer, seller or distributor who shall conceal, substitute, dispose or destroy any drug as may have been segregated and sealed by the FDA, or who shall break, alter or tamper any mark or seal used by the FDA to identify those segregated drugs as provided for under Section 6(a) of the Act. Any other person who breaks, alters or tampers any mark or seal used by the FDA to identify the segregated drugs shall suffer the penalty of not less than six (6) months and one (1) day, but not more than six (6) years imprisonment; or

e) if, as a result of the use of the drug found to be counterfeit, the illness sought to be cured is aggravated or physical injury or suffering results therefrom, a punishment of imprisonment from twelve (12) years to fifteen (15) years and a fine ranging from One hundred thousand pesos (P100,000.00) to Five hundred thousand pesos (PHP500,000.00) shall be meted out; or

f) should a counterfeit drug be the proximate cause of death of a victim, who unknowingly purchased and took a counterfeit drug, the penalty of life imprisonment and a fine of Five hundred thousand pesos (PHP500,000.00) to Five million pesos (PHP5,000,000.00) shall be imposed.

In case any act prohibited in Section 4 of the Act or Rule III hereof is also punishable under other laws, the offender shall, if warranted by the evidence, be prosecuted under the law prescribing the highest penalty.

When the sale, offering for sale, donation, distribution, trafficking, or brokering of counterfeit drugs, or the sale of any punch, dye, plate or any other equipment or instrument designed to print, imprint or reproduce the trademark, trade name or other identifying mark of another registered producer or any likeness thereof, upon any drug product or device or its container or label without authority from the legitimate owners of the trademark or trade name, as prohibited in Section 4 of the Act or Rule III hereof is committed by, through and with the use of online service, the same shall also be covered by the relevant provisions of Republic Act No. 10175 or the "Cybercrime Prevention Act of 2012". *Provided*, that the penalty to be imposed shall be one (1) degree higher than that provided under the Act.

RULE IX. FINAL PROVISIONS

Section 1. *Separability.* If any part or provision of these rules and regulations shall be held to be unconstitutional or invalid, other parts or provision hereof which are not affected thereby shall continue to be in full force and effect.

Section 2. *Repealing Clause.* All administrative issuances or parts thereof inconsistent herewith are hereby repealed or modified accordingly.

Section 3. *Amendments.* These rules and regulations may be amended, modified or supplemented when effective implementation and enforcement of R.A. 8203 would require.

The FDA may further establish and provide graduated imposable administrative penalties within the minimum, medium and maximum range consistent with the provisions of the law.

Section 4. *Effectivity.* This Order shall take effect thirty days (30) after its publication in two newspapers of general circulation and submission of three (3) certified copies to the University of the Philippine Law Center, Office of the National Administrative Register.

Issued this 4th day of October 2019, in Manila, Philippines.

Approved by:

FRANCISCO T. DUQUE III, MD, MSc.
Secretary of Health

Office	HRT/ FDA	HPDPB	OSEC
Initial	ROLANDO ENRIQUE D. DOMINGO, MD, DPBO Undersecretary/ Officer-in-Charge	MAYLENE M. BELTRAN, MPA, CESO III Director IV	ATTY. FATIMA P. LAPERAL Head Executive Assistant
Date			

billowing from a burnt car. Witnesses said the mangled body of the attacker was taken for further identification as an anti-bomb squad secured the location.

Indonesia, the world's most populous Muslim nation, has been battling militants since bombings on the resort island of Bali in 2002 killed 202 people, mostly foreign tourists.

Police officers stand guard at the gate of the local police headquarters following a suicide bombing attack at the compound in Indonesia yesterday. AP

South African gin infused with elephant dung

MOSSEL BAY (AP) — The makers of a South African gin infused with elephant dung swear their use of the animal's excrement is no gimmick.

The creators of Indlovu Gin, Les and Paula Ansley, stumbled across the idea a year ago after learning that elephants eat a variety of fruits and flowers and yet digest less than a third of it.

"As a consequence, in the elephant dung, you get the most amazing variety of these botanicals," Les Ansley said during a recent visit to their operations. "Why don't we let the elephants do the hard during which a wildlife ranger described an elephant's digestive process.

Weeks later, he said his wife woke him up in the middle of the night with the inspiration. "OK," I said sleepily. "Let's give this a bash. Let's see how it works out."

The first batch of elephant dung came by mail from the park where they had taken their safari. Then the couple, both scientists, puzzled for a while before working out the gin-making process.

Now they collect the dung themselves, using their bare hands.

of its license to do business shall be the medium administrative penalty.

Provided, that if the Respondent or any of his officer or agent shall conceal, substitute, dispose or destroy any drug/medicine as may have been segregated and sealed by the FDA or who shall break, alter or tamper any mark or seal used by the FDA to identify those segregated drugs; or as a result of the use of the drug/medicine found to be counterfeit, the illness sought to be cured is aggravated or physical injury or suffering results therefrom, the maximum imposable fine of Five hundred thousand pesos (PHP500,000.00) and permanent closure of establishment as well as the revocation of its license to do business shall be imposed.

Section 3. ***Maximum Penalty.*** An administrative fine of Five hundred thousand pesos (PHP500,000.00) and permanent closure of the establishment concerned as well as the revocation of its license to do business shall be the maximum administrative penalty.

FRANCISCO T. DUQUE III, MD, MSc.
Secretary of Health

Office	HRT/FDA	HPDPB	OSEC
Initial	ROLANDO ENRIQUE D. DOMINGO, MD, DPBO Undersecretary/ Officer-in-Charge	MAYLENE M. BELTRAN, MPA, CESO III Director IV	ATTY. FATIMA P. LAPERAL Head Executive Assistant
Date			

Keywords	Counterfeit Drug/ Medicine
Related Issuances	RA No. 8203, RA No. 9711, Executive Order No. 292 or the Administrative Code of 1987

P.Star – Nov. 14, 2019

"As a consequence, in the elephant dung, you get the most amazing variety of these botanicals," Les Ansley said during a recent visit to their operations. "Why don't we let the elephants do the hard work of collecting all these botanicals and we will make gin from it?" he recalled his wife suggesting.

Her idea came after a safari their safari. Then the couple, both scientists, puzzled for a while before working out the gin-making process.

Now they collect the dung themselves, using their bare hands.

They described the gin's flavor as "lovely, wooded, almost spicy, earthy" and one that changes subtly with the seasons and location.

PHILIPPINE NATIONAL CONSTRUCTION CORPORATION

INVITATION TO BID

The Philippine National Construction Corporation (PNCC), through its Task Force Asset Disposal (TFAD), invites interested bidders to submit bids for various junk/used equipment and scrap materials located at the following locations:

1. PNCC - Bicutan, Paranaque City.
2. TRB - Skyway Warehouse Taguig/Bicutan
3. Philphos - Isabel, Leyte

Bid documents will be issued from November 14, 2019 upon payment of a non-refundable fee of ₱1,000. All items may be inspected during office hours from Monday to Thursday only.

All sealed bids must be received at the TFAD Office, PNCC Bicutan, Parañaque City on or before 10:00 AM, December 18, 2019. The bids will be opened and tabulated shortly thereafter in the presence of the bidders. Bid deposits equivalent to Ten Percent (10%) of the bid amount, in the form of Cash or Manager's Check in Philippine currency, must be submitted together with the sealed bids. Bidders may submit bids either for a single or several items.

PNCC reserves the right to reject any or all bids, to waive any formality therein or to accept such bids as may be considered most advantageous to the Company. The decision of PNCC is final and binding.

Interested bidders may call PNCC/TFAD (Moses or Amiel) at tel. # 846-3414 for further details.

YOLANDA C. MORTEL
Head, MMD-TFAD

P.S. November 14 & 15, 2019

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Clinton: UK voters must see Russian influence report

LONDON (AP) — Hillary Clinton says she's "dumbfounded" that the UK government has failed to release a report on Russian influence in British politics before the country holds a national election next month.

The former US presidential candidate told British media that the public needs to know what is in the report by Parliament's Intelligence and Security Committee before voters go to the polls on Dec. 12.

British Prime Minister Boris Johnson's government has said it needs more time to review the security implications of the report before it is released.

Critics, however, alleged the report is being withheld until after the election because it is embarrassing to Johnson's Conservative Party, which is trying to win a majority and push through Johnson's Brexit plan to take Britain out of the European Union.

"I'm dumbfounded that this government won't release the report ... because every person who votes in this country deserves to see that report before your election happens," Clinton told the *BBC* on Tuesday.

"There is no doubt ... that Russia in particular is determined to try to shape the politics of Western democracies, not to our benefit but to theirs."

Former Special Counsel Robert Mueller's investigation into the 2016 US presidential election found that Russia interfered in the vote in a "sweeping and systemic" fashion.

US President Donald Trump, who won that vote, has dismissed the Mueller report's conclusions, but the investigation has put Russia into the crosshairs of a debate on the integrity of elections worldwide.

Clinton also spoke about the British report with the *Guardian* newspaper as she promoted "The Book of Gutsy Women," written with her daughter, Chelsea.

The former US Secretary of State said she wished she had been more "gutsy" in exposing Russian efforts to influence the 2016 US presidential election.

"I am, as a great admirer of Britain, concerned, because I can't make sense of what is happening," Clinton told the *Guardian*. "We have a president who admires dictators and takes their help and does all kinds of crazy stuff. So we need you to be the sane member of this partnership going forward."

The Intelligence and Security Committee began its investigation following allegations of Russian interference both in the 2016 US election and the British referendum on the country's EU membership earlier that year.