DRAFT

ADMINISTRATIVE ORDER
No. ______________________

Subject: Rules and Regulations on Registration of Household/Urban Pesticides, and For Other Purposes

I. BACKGROUND AND RATIONALE

Evaluation of the safety and efficacy of household/urban pesticides (H/UPs) as one of the health products under the jurisdiction of the FDA is essential. These products are inherently toxic products relative to the other health products being regulated by the FDA, namely food, drugs, cosmetics, and devices, regulated by the FDA.

These products have great impact on public health, as they are designed to control the vermin or vectors on infectious diseases. The product active ingredients, additives, formulation, indication, use, storage condition, and disposal should adhere to international standards to protect the public, applicators and the receiving environment. According to the World Health Organization, impurities formed during manufacture of the pesticide or by interaction in unstable formulations can increase product toxicity to humans and the environment. Applying products that are lower in active ingredient content than declared could result in monetary loss and application of a sub-lethal dose of pesticide, leading to ineffective control and promotion of the development of resistance.

Products or formulations with inferior physiochemical properties, such as suspensibility, emulsification or particle size characteristics, can also result in inadequate application and possibly increase the degree of risk for personnel, who may come into greater contact with the pesticide and/or pesticide contaminated application equipment.

It is also important that all household and urban pesticides are not harmful to pet animals when used according to the product label.

The first issuance on Household Hazardous Substances (HHS) was Presidential Decree No. (PD) 881, dated 30th January 1976, empowering the Secretary of Health to regulate the labeling, sale and distribution of Hazardous Substances. Pursuant to that, the Secretary of Health issued Administrative Order No. 303 s. 1976 to provide guidelines on the registration of HHS and licensing of establishments engaged in the sale and manufacture of HHS under the Food and Drug Administration (FDA).
On the 17th January 1977, Administrative Order No. 312 was issued by the Secretary of Health. It classified or listed fertilizers, pesticides, insecticides and other economic poisons, together with room fresheners and deodorizers, as HHS under Category V.

On May 30, 1977, PD No. 1144 was issued, creating the Fertilizer and Pesticide Authority (FPA) and abolished the Fertilizer Industry Authority. The PD mandated the FPA to have jurisdiction over all existing handlers of pesticides, fertilizers and other agricultural chemical inputs. As a result, the Ministry of Health issued Administrative Order No. 39 s. 1979 which delisted fertilizer, insecticides and other pesticides under Category V and, thereby, transferred the regulatory jurisdiction over them to FPA from the FDA.

In a final decision dated February 8, 2007, the Supreme Court ruled over in the FPA vs. Manila Pest Control Co. (MAPECON) and Woodrow Catan, G.R. No. 161594. It ruled that the FPA did not have jurisdiction or regulatory power over the acts and business operations of Manila Pest Control Company (MAPECON) and declaring that only agricultural pesticides and not urban pest control products fall under the jurisdiction of the FPA. Urban pest control or pesticide use in households, offices, hotels and other commercial establishments has nothing to do with agriculture.

The FDA issued DOH-BFAD Advisory No. 2008-003, re: Import Permits; Initial Registration and Renewal of Existing Certificates of Product Registration Covering Household Pesticide Products, as well as. Licenses to Operate of Entities Manufacturing or Importing/Exporting/Distributing such Products and Raw Materials, as a regulatory measure or as a necessary consequence of the Supreme Court decision dated 08 February 2007 holding that the Fertilizer and Pesticides Authority (FPA) has jurisdiction only over agricultural pesticides and not to pesticides used in household, business establishments, and offices in urban areas, registration of such products, as well as, licensing of entities engaged in the manufacture or importation/distribution of the products or raw materials, which shall now be under the purview of the Department of Health, through the Bureau of Food and Drugs, which is vested by law with the power to regulate household hazardous substances, considering that the above pesticides are inherently hazardous.

Republic Act No. 9711, otherwise known as “The FDA Act of 2009”, states that “the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, or retail of any drug or device; the manufacture, importation, exportation, transfer or distribution of any food, cosmetics, household hazardous substances or urban pesticides; or the operation of a radiation facility or pest control establishment without the appropriate authorization from the FDA is prohibited.”
This Administrative Order is being issued to provide guidelines for registration of H/UPs that are manufactured, distributed, advertised, promoted and marketed, sold and offered for sale or use, and retailed in the country to protect the health, welfare and interest of the public and consumers.

II. OBJECTIVES

The objectives for issuing this Administrative Order are as follows:

a. To protect the health and welfare of the consumers and the general public especially infant, children and old people, against banned, illegal and unregistered household/urban hazardous products/urban pesticides, and

b. To provide guidelines on licensing of establishments engaged in manufacture, trade, distribution (importers, exporters, wholesalers), retail or urban/household pesticides.

III. SCOPE

This Administrative Order shall apply to all establishments engaged in the manufacture and distribution, i.e. import, export, wholesale and trade, as well as retailers of Household/Urban Pesticides.

It shall not cover pesticides under the jurisdiction of FPA, as mandated by law.

IV. DEFINITION OF TERMS

The following terms are defined for clarity:

1. Authorization is a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and/or where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption, or any similar document.

2. Bioefficacy Test is a scientific study conducted to show, demonstrate or substantiate a claim of efficacy against pests as indicated in the label or as claimed by the applicant. The data or information generated from bioefficacy studies shall be based on actual experiment based on a hypothesis consistent with the mechanism of action.
3. Certificate of Product Registration (CPR) is a document issued by the FDA for the purpose of authorization to sell or offer for sale or use after a product has met the standard of safety, efficacy and quality.

4. Distribute means the delivery or sale of any household/urban pesticides for purposes of distribution in commerce, except that such term does not include the manufacture or retail of such product.

5. Distributor/Importer/Exporter means any establishment that imports, exports or locally procures raw materials, active ingredients and/or finished products for wholesale distribution to other establishments or outlets.

6. Household/Urban Pesticide (H/UP) refers to (1) any material or mixture of substances used for the control of pests (e.g. flies, mosquitoes, cockroaches, ants, rodents) found in places of human habitation, work and recreation. They shall include pesticides used for the control of pest in homes, yards, and gardens but shall exclude chemicals used in commercial agricultural production, golf courses, maintenance, pest extermination in industrial products and related uses; (2) products that are intended for use in domestic or commercial establishments for the control of flying, crawling and structural insect pests (e.g. termiticides, rodenticides and wood preservative). It also refers to any substance or product, or mixture thereof, including active ingredients, adjuvants and pesticide formulations, intended to control, prevent, destroy, repel or mitigate directly or indirectly, household/urban pest. It shall be understood to include insecticide, fungicide, bactericide, nematicide, herbicide, molluscicide, avicide, rodenticide, desiccant and the like not intended for agricultural use.

The H/UPs can be classified as
a. For Ready-to-Use H/UPs are FDA-registered products intended for dwelling places, homes, classrooms, or offices or similar places where people stay or frequent but do not require further dilution. But some ready to use products may need to be transferred to a gadget/applicator. The CPR will indicate if a product is ready-to-use. Retailers selling or offering for sale or use ready-to-use products do not require FDA LTO.

b. For Professional Use H/UPs are FDA-registered products intended to be applied as fumigants by FDA-licensed operator, FDA-certified applicators and FDA-trained pesticides handlers. The CPR will indicate if a product is restricted use. Retailers selling or offering for sale or use for professional use products requires FDA LTO.

c. For Institutional Pest Control Program Use of H/UPs are FDA-registered products intended to be applied in construction sites, establishments, dwelling places or
public places under a pest control program. The CPR will indicate if a product is for institutional use.

7. Household/Urban Pesticide Establishment means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale or use, distribution, donation, transfer, testing, promotion or advertisement of household/urban pesticide products including the facilities and installations needed for its activities.

8. Label means a display of written, printed, or graphic matter on the immediate container, or other materials affixed thereto, of any article. Any word, statement or other information appearing on the label required under authority of the FDA Act of 2009 or other relevant laws shall be deemed complied with if such word, statement or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or easily legible through the outside container or wrapper.

9. Manufacturer means an establishment engaged in any and all operations involved in the production of household/urban pesticides including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.

10. Pesticide Registration means the process whereby the responsible regulatory agency approves the sale and use of a household/urban pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment.

11. Products for Use by Consumer means products that are used, applied as ready-to-use space spray or surface spray for knockdown and residual action. They are commonly formulated as aerosol or as liquid end-use product applied with manually operated pressure spray. Other forms include pest strips, baits, lotions, chalks, balls, insect repellants, patches, coils, impregnated nets with insect repellant and others. (See definition for “For Ready-to-Use H/UPs”)

12. Raw Materials mean starting material which includes technical grade active ingredient which has a pesticidal activity and inert ingredients or additives used in the production of finished pesticide product.

13. Stability Study is a scientific study performed to show data, demonstrate or substantiate a claimed shelf-life of a product. Stability tests are carried out to
determine the acceptable period of storage at a specified condition within which the pesticide product still meets its established specifications or claim of efficacy.

14. Toxicity Studies are studies performed in vivo or on animals that is initiated by exposure to a chemical, physical or biological agent, and to determine the toxicity level, adverse effects and to show a series of events, like toxidrome observed for a product for the purpose of classification or categorization. The toxicity reports containing sets of data or information from an experiments for the purpose of risk assessment and risk analysis of the product.

IV. GENERAL POLICIES AND STANDARDS

1. The manufacture, importation, exportation, sale, offering for sale or use, donation, distribution, transfer, promotion, advertisement, or sponsorship of any H/UPs that is adulterated, unregistered or misbranded is prohibited.

2. Only those establishments with valid FDA LTOs may apply for a CPR.

3. Applicants shall submit technical dossier to demonstrate the safety, efficacy, and quality of the product being registered.

4. All technical materials / active ingredients used in the manufacture of the H/UP must be registered with FDA.

5. The FDA shall work closely with the DOH National Center for Non-communicable Diseases, other government agencies with mandate to regulate pesticides like the Department of Agriculture, other regulatory agencies in other countries, foreign governments, and international organizations like the WHO and the FAO to develop and strengthen the FDA standards and approaches to the sound management of pesticides.

6. The FDA shall honor international agreements have been developed on different aspects of pesticides to strengthen public health and environmental protections across the globe, such as the Montreal Protocol on substances that deplete the ozone layer, Rotterdam Convention on the prior informed consent (pic) procedure for certain hazardous chemicals and pesticides in international trade, and Stockholm Convention on persistent organic pollutants (POPs).

7. Inclusion in the list of banned or prohibited finished products for chemical or biological pest control, active and raw ingredients or additives of pesticides, and
combinations thereof, of the Fertilizer and Pesticide Authority, Department of Agriculture (FPA-DA) is a ground for disapproval of application.

8. Products that have the same formulation but in different packaging presentation, different containers, different mode of administration, volume of content or containers, shall have separate and unique applications for initial registration.

9. All products shall be evaluated for its safety to pet animals, namely dogs and cats, when used according to the product label.

V. GUIDELINES FOR REGISTRATION OF PRODUCTS

1. Requirements For Initial Product Registration
   1.1 Revised Assessment Slips
   1.2 Notarized Application Form and Declaration
   1.3 FDA Worksheet: PART I ONLY
   1.4 Copy of Valid License to Operate: 
   1.5 Any of the following:
      Certificate of Free Sale
      Certificate of Good Manufacturing Practice
      Manufacturing License or ISO Certificate
      *Duly authenticated by the Consulate of the Philippine Embassy from the country of origin.
   1.6 Composition of the finished product expressed in percent
   1.7 Safety Data Sheet of the Raw Material(s) including the technical specifications of the active ingredients.
   1.8 Certificate of Analysis of the finished product
   1.9 Technical Specification of the finished product
      1.9.1 Appearance, color, state, odor
      1.9.2 Melting Point
      1.9.3 Boiling Point
      1.9.4 Vapor Pressure
      1.9.5 Density of Specific Gravity
      1.9.6 Solubility in water and solvents
      1.9.7 Suspensibility/Emulsifying Characteristics
      1.9.8 Known capability/incompatibility with other pesticide or Active ingredients
      1.9.9 Flash point and other indications of flammability (If product contains combustible liquid)
      1.9.10 pH
1.10 Certificate of Analysis of the Finished Product duly signed and dated referring to the same batch/lot number of the sample submitted; written/translated in English on the letterhead of manufacturer shall include the following:

1.10.1 Name and batch number of sample submitted
1.10.2 Complete specifications, methods and limits stated on technical specifications of the finished product (II.6)
1.10.3 All test results based on technical specifications of finished product stating actual numerical value (when applicable)

1.11 Manufacturing procedure
1.12 Complete Test Methods done on the finished product
1.13 Unattached legible, comprehensive and indelible specimen of all labelling materials per pack size [e.g. outer, immediate, package insert (if applicable) (AO 311 s. 1977)/GHS.

1.14 Picture of the finished commercial product.
1.15 Bioefficacy study
1.16 Toxicity study
1.17 Stability study
1.18 Substantiation of product claims, as applicable

2. Requirements For Renewal of Product Registration

2.1 Revised Assessment Slips
2.2 Notarized Application Form and Declaration
2.3 FDA Worksheet: PART I ONLY
2.4 Copy of Valid License to Operate
2.5 Original copy of Certificate of Product Registration (CPR)
2.6 Composition of the finished product expressed in percent
2.7 Technical Specification of the finished product
   2.7.1 Appearance, color, state, odor
   2.7.2 Melting Point
   2.7.3 Boiling Point
   2.7.4 Vapor Pressure
   2.7.5 Density of Specific Gravity
   2.7.6 Solubility in water and solvents
   2.7.7 Susceptibility/Emulsifying Characteristics
   2.7.8 Known capability/incompatibility with other pesticide or Active ingredients
   2.7.9 Flash point and other indications of flammability (If product contains combustible liquid)
   2.7.10 pH
2.8 Certificate of Analysis of the Finished Product duly signed and dated referring to the same batch/lot number of the sample submitted; written/translated in English on the letterhead of manufacturer shall include the following:

2.8.1 Name and batch number of sample submitted
2.8.2 Complete specifications, methods and limits stated on technical specifications of the finished product (II.6)
2.8.3 All test results based on technical specifications of finished product stating actual numerical value (when applicable)

2.9 Manufacturing procedure
2.10 Complete Test Methods done on the finished product
2.11 Unattached legible, comprehensive and indelible specimen of all labelling materials per pack size [e.g. outer, immediate, package insert (if applicable) (AO 311 s. 1977)/GHS.

2.12 Picture of the finished commercial product.
2.13 Bioefficacy study
2.14 Toxicity study
2.15 Stability study
2.16 Substantiation of product claims, as applicable

3. Changes and Amendments to a CPR

All modifications on the registration of products shall be approved by the FDA. A letter of request has to be submitted for any amendment to the CPR.

3.1 Change in business name of the manufacturer/distributor

3.1.1 Valid LTO reflecting the new business name and address of the manufacturer/trader/importer with the source reflected on the LTO.
3.1.2 Valid original CPR
3.1.3 Complete labeling requirements reflecting the change (primary, secondary and inserts, if applicable)

3.2 Change in Ownership

3.2.1 Valid LTO reflecting the source
3.2.2 Termination of Contract/Deed of assignment
3.2.3 Agreement of the manufacturer and the new trader/importer/distributor
3.2.4 Valid original CPR
3.2.5 Complete labeling requirements reflecting the change (primary, secondary and inserts, if applicable)

3.3 Change in product name (brand name/variant name, etc.)

3.3.1 Valid original CPR
3.3.2 Valid LTO
3.3.3 Complete labeling requirements reflecting the change (primary, secondary and inserts, if applicable)
3.3.4 Affidavit of no change in the formulation
3.4 Extension of use or claim:
3.5 Change in rate, timing or frequency of application or method of application
3.6 Request for change in formulation, additional or new source of finished product, and change of manufacturer/address of manufacturer shall require initial registration.

3.4 Extension of use or claim:
3.4.1 Local Bio-efficacy study to support the claim
3.4.2 Letter of request
3.4.3 Valid original CPR
3.4.4 Valid LTO
3.4.5 Complete labeling requirements reflecting the change

3.5 Change in rate, timing or frequency of application or method of application

Study or studies that will justify request for change in rate, timing or frequency of application, or method of application

3.6 Request for change in formulation, additional or new source of finished product, and change of manufacturer/address of manufacturer shall require initial registration.

VII. FEES AND CHARGES

Fees and charges shall be based on existing guidelines of the FDA, which may be accessed through the FDA Website (www.fda.gov.ph).

VII. PENALTIES

H/UP establishments engaged in the manufacture, importation, exportation, sale, offered for sale, distribution, donation, transfer, use, testing, promotion, and/or advertising of household/urban pesticide products including the facilities and installations needed for its activities who are found to be operating outside the rules and regulations of FDA will be subject to sanctions and penalties as prescribed by Republic Act No. 9711.

VII. APPROVAL AND VALIDITY

Registration of product shall be issued only when the applicant has complied with all the requirements and has met the standards of the FDA.

The validity of the CPR shall be for 5 years.
VIII. SEPARABILITY CLAUSE

If any part or term of provision of this order shall be declare invalid or unenforceable the validity or enforceability of the remaining portions or provisions shall not be affected and this order shall be construed as if it did not contain the particular invalid or enforceable part, term or provision.

IX. REPEALING CLAUSE

All other administrative issuances, bureau circulars and memoranda and other regulations inconsistent with this Order are hereby withdrawn, repealed and /or revoked accordingly.

X. EFFECTIVITY CLAUSE

This Administrative Order shall take effect in fifteen (15) days after publication in a newspaper of general circulation.

ENRIQUE T. ONA, M.D.
Secretary of Health

<table>
<thead>
<tr>
<th>FDA</th>
<th>HPDPB</th>
<th>OSEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>KENNETH Y. HARTIGAN-GO, MD</td>
<td>LILIBETH C. DAVID, MD, MPH, MPM</td>
<td>JAIME Y. LAGAHID, MD, MPH</td>
</tr>
<tr>
<td>Acting Director IV</td>
<td>Directo IV</td>
<td>Head Executive Assistant</td>
</tr>
</tbody>
</table>

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900
Fax +63 2 807 0751
Website: www.fda.gov.ph
Email: info@fda.gov.ph