IMPLEMENTING GUIDELINES FOR THE IMPLEMENTATION OF BOARD REGULATION NO. 6, SERIES OF 2007, ENTITLED CLASSIFYING TOLUENE-BASED CONTACT CEMENT PRODUCTS WITHOUT AT LEAST FIVE PERCEN...

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WHEREAS, the Board promulgated Board Regulation No. 6, Series of 2007 classifying as dangerous drugs toluene-based contact cement products without at least five percent (5%) mustard oil content;

WHEREAS, the Board, under Board Resolution No. 30, Series of 2008, directed the Legal Affairs Division of the Dangerous Drugs Board Secretariat to draft the implementing guidelines for the aforementioned Board Regulation No. 6;

WHEREAS, the Legal Affairs Division, in consultation with the Committee on Public Hearings, Technical Working Group, manufacturers and importers of contact cement products and other stakeholders, has submitted to the Board the draft of the required guidelines for the said Board Regulation No. 6;

NOW, THEREFORE, be it RESOLVED, as it is hereby RESOLVED, to promulgate these Implementing Guidelines:

Article I
Coverage

SECTION 1. Coverage - These Implementing Guidelines shall cover all importers, exporters, manufacturers, distributors, retailers, end-users and handlers of Toluene-based contact cement products;

Article II
Definition of Terms

SECTION 1. Definitions – The following are the definition of the terms used in these Implementing Guidelines:

a. “Contact Cement” - is a synthetic adhesive that is applied to one or both of the surfaces to be joined, with the surfaces then being brought into contact;

b. “Dangerous Drugs” include those listed in the Schedules annexed to the 1961 UN Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and in the Schedules annexed to the 1971 UN Convention on Psychotropic Substances, which are annexed to R.A. 9165, as well as those classified as such by the Dangerous Drugs Board pursuant to Section 93, Article XI of RA 9165;

c. “Distribution” means the sale of Toluene-based contact cement products on a wholesale basis;

d. “Export” means any physical departure of Toluene-based contact cement products from the territory of the country which requires customs declaration;

e. “Import” means any physical introduction of Toluene-based contact cement products into the territory of the country which requires customs declaration;

f. “Industrial Use” - is the use of Toluene-based contact cement products in the normal course of the industry of the end-user;

g. “Manufacture” means the production, preparation, compounding or processing of Toluene-based contact cement products, either directly or indirectly or by extraction from substances of natural origin or independently by means of chemical synthesis, and shall include any packaging or repackaging of such substances, design or configuration of its form, or labeling or re-labeling of its container;

h. “Mustard Oil” is a colorless to pale yellow pungent irritating oil that is obtained by distillation from the seeds, usually of black mustard, after expression of the fatty oil and maceration with water, or through chemical synthesis, that consists largely of a chemical allyl isothiocyanate, a volatile compound with a characteristic of pungent odor capable of inducing eye tears;

i. “PDEA” refers to the Philippine Drug Enforcement Agency;

j. “Person” means any person or entity, natural or juridical, including among others, a corporation, partnership, trust or estate, joint stock company, association, syndicate, joint venture or other unincorporated organization or group capable of acquiring rights or entering into obligations, engaged in the importation, manufacture, distribution and sale of contact cement products classified as dangerous drugs;

k. “Retail” means the sale of Toluene-based contact cement products on retail basis;

l. “ Toluene” - is a colorless, flammable, toxic liquid hydrocarbon aromatic compound with a chemical formula of C6H5CH3 which is the methyl derivative of benzene, 653 found in coal-tar light oil and in petroleum and is obtained chiefly from the processing of petroleum fractions. It is included in Table II of the 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

Article III
General Guidelines

SECTION 1. Dangerous Drugs – Pursuant to Section 2 of Board Regulation No. 6 Series of 2007, Toluene-based contact cement products without at least five percent (5%) mustard oil content are classified as “Dangerous Drugs”. (It shall hereafter be referred to in these Implementing Guidelines as the “dangerous drug”);

SECTION 2. Mustard Oil – The mustard oil may be natural or synthetic. The required mustard oil content shall be based on the total weight/volume of the Toluene content of the contact cement product as stated in the product label, carton or other container;

SECTION 3. Markings of Mustard Oil Content in Product Labels - The product labels, cartons or other containers of Toluene-based contact cement products with at least five percent (5%) mustard oil content shall indicate the presence of such additive and the percentage content thereof relative to the total weight/volume of the Toluene content of the contact cement product;

SECTION 4. Obnoxious Odor and Volatility - The obnoxious odor of the contact cement with at least five percent (5%) mustard oil shall be present and maintained from the time of manufacture or importation of the product until the same is utilized by the end-user, and/or the volatility of the mustard oil shall be less than that of the toluene content of the product;

SECTION 5. Effect of Non-Compliance with Sections 3 and 4 hereof – The non-compliance with Sections 3 and 4 of this Article shall make the product a “dangerous drug” notwithstanding the presence of at least five percent (5%) of mustard oil thereof.

Article IV

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Licensing and Permit Requirements for Transactions of Contact Cement Products Classified as Dangerous Drugs

SECTION 1. License and Permit Requirements

a. No person shall manufacture, distribute or retail the dangerous drug, except pursuant to and in accordance with the terms and conditions of a license granted by the PDEA.

b. No person shall import, export, bring into the Philippines in transit, or redirect from the Philippines while in transit, the dangerous drug except pursuant to and in accordance with any of the terms or conditions of:

1. License issued by the PDEA authorizing the person to carry out such activities; and

2. Separate import permit, export permit, transit permit or redirection permit, as the case may be, authorizing the person to carry out the specific transaction as indicated in the permit application.

c. Transfer or delivery of the dangerous drug from a license holder to another license holder, except retail sales, shall be made with the prior approval of the PDEA.

d. Unless specified otherwise, the following groups of activities are deemed to be independent of each other and shall have separate registration and license:

1. Importation, for wholesale distribution or as industrial end-user
2. Exportation
3. Manufacturing
4. Wholesale distribution
5. Retail
6. Storage of the dangerous drug in separate address or addresses
7. Industrial use from local source
8. Laboratory analysis or technical or teaching program

e. A person shall secure from the PDEA as many licenses as he has places of business and/or activities. Any person conducting two or more types of business at the same location shall secure from PDEA a license for each type of business. For this purpose, the PDEA shall issue a consolidated license detailing the type of activities and corresponding license.

SECTION 2. Application for Licenses

a. An applicant shall apply in writing to the PDEA for the grant of a license and specify:

1. Full name, private and business address of the applicant;
2. Each activity to which the application relates;
3. If the applicant is a company, the full name and residential address of each director and the company secretary;
4. If the applicant proposes to engage in the activity under a business name, that name;
5. Brand name of the dangerous drug to which the application relates and the address of each place where the proposed activity would be carried out;
6. Premises where the dangerous drug will be stored;
7. Security arrangements that would be implemented at each address (storage, access, type of building construction, alarm systems, adequacy of supervision over employees having access, procedure of handling guest and maintenance personnel, adequacy of system for monitoring receipt), and the distribution and disposition of the dangerous drug;
8. Name, residential address and qualification of each person under whose supervision the activity would be carried out:
9. Whether the person (and if the company, any director or the company secretary) has ever been convicted in

the Philippines or elsewhere for a serious offense or any offense however described relating to trafficking in dangerous drugs or their respective preparations;
10. Volume estimate in the forthcoming year and volume statistics for the past year of dangerous drugs; in the case of manufacture, the extraction, manufacturing and denaturing procedure to be used, name and quantities of the substances and raw materials to be used, estimates relating to the dangerous drug produced;

b. An application for license shall be accompanied by:

1. A plan of each of the relevant premises, indicating where the dangerous drug would be stored, and the location and nature of any security device(s);
2. Registration with the Philippine Export Zone Authority or Board of Investments, as applicable;
3. Business permit or certificate of registration issued by the local government unit, Department of Trade and Industry or Securities and Exchange Commission;
4. National Bureau of Investigation (NBI) clearance;
5. The prescribed fee; and
6. Other requirements as the PDEA may prescribe.

SECTION 3. Application for Import, Export or Transit Permits

a. An application for an import, export or transit permit shall be made in writing by a licensee to the PDEA at least fifteen (15) working days in advance before the transaction is to take place and specify:

1. The full name and address of the importer, exporter, carrier, consignee and if known, of any ultimate consignee;
2. In the case of a proposed import, export or transit of the dangerous drug, its trade name or brand name;
3. The quantity, mass and volume of the dangerous drug;
4. The date or period within which the planned import, export or transit is to take place;
5. The planned transport route, if known, including the planned point of entry or exit from the Philippines; and
6. In the case of proposed import of the dangerous drug to a bonded warehouse, the identity and address of the warehouse.

b. In the case of a proposed export of the dangerous drug, the import permit issued by the government of the foreign State of intended import shall be attached to the application for export permit.

SECTION 4. Contents and Conditions of Licenses

a. A license issued by the PDEA shall specify:

1. The full name and address of the licensee;

2. Each activity to which the license relates;

3. The brand name of the dangerous drug to which the license relates;

4. The address of each place and premises at which:

i. the licensed activity is to be carried out; and
ii. the dangerous drugs is to be stored;

5. Such terms and conditions as are necessary and reasonable for ensuing the proper:

i. carrying out and supervision of the licensed activity
ii. establishment, maintenance and preservation of record relating to that activity;
iii. reporting to the PDEA in relation to the carrying out of that activity;

6. In the case of any license to import, export or bring to the Philippines in transit the dangerous drug, the

condition that a separate import, export or transit permit be first obtained in relation to any such transaction before it takes place; and

7. Official receipt number of prescribed fee;

SECTION 5. Duration of Licenses and Permits

a. A license shall remain in force for one year, unless earlier surrendered, suspended or revoked;

b. A permit shall only remain in force for such period as may be specified in it, which in the case of an import permit for the dangerous drug shall not exceed six (6) months, and in the case of export permit or transit permit for the dangerous shall not exceed three (3) months.

SECTION 6. Fees - Unless specifically exempted under any Board issuance, special law or charter, the required fees per year for the corresponding licenses are as follows:

Type of License

Annual Fee

a. License to Import Toluene-based Contact Cement Products Without At Least Five Percent (5%) Mustard Oil (for wholesale distribution or as industrial end-user) (LTI) P5,000.00

b. License to Export Toluene-based Contact Cement Products Without At Least Five Percent (5%) Mustard Oil (LTE) P5,000.00

c. License to Manufacture Toluene-based Contact Cement Products Without At Least Five Percent (5%) Mustard Oil (LTM) P5,000.00

d. License to Distribute Toluene-based Contact Cement Products Without At Least Five Percent (5%) Mustard Oil (LTD) P5,000.00

e. License to Retail Toluene-based Contact Cement Products Without At Least Five Percent (5%) Mustard Oil (LTR) P3,000.00

f. License to Store Toluene-based Contact Cement Products Without At Least Five Percent (5%) Mustard Oil (when the address of the facility is separate and distinct from the office address of the license holder) (LTS) P3,000.00

g. License to Procure from Local Source Toluene-Based Contact Cement Products Without At Least Five Percent (5%) Mustard Oil for Industrial Purposes (LTPI) Corporation P3,000.00

Partnership P2,000.00

Cooperative P1,000.00

Individual P500.00

h. License to Conduct Laboratory Analysis or Technical Research or Instructional Program Using Toluene-Based Contact Cement Products Without At Least Five Percent (5%) Mustard Oil (LTC) P500.00

SECTION 7. Licensee to Deal Only with Other Licensee – Except in retail sales, a license holder shall transact the dangerous drug only to another license holder.

Article V
Industrial Use

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SECTION 1. Dangerous Drug Control Book – A holder of an LTI license (as industrial end-user) or LTPI license shall maintain a Dangerous Drug Control Book, computerized or manual and registered with the PDEA, to record the daily issuances of the dangerous drug to its workers directly handling the said dangerous drug. It shall be kept and maintained under a secure place by the authorized custodian of the dangerous drug and subject to inspection by the PDEA at any reasonable time and day. The book shall, among others, contain the following information:

a. Date and time of issuance or receipt of the dangerous drug;
b. Full name of the worker receiving or returning the dangerous drug;
c. Quantity of the dangerous drug issued or received;
d. Signature of the worker receiving or returning the dangerous drug; and
e. After the last entry for the day, the day's summary of the actual usage (issued minus returned) of the dangerous drug per worker.

SECTION 2. Submission of Report to the PDEA – The aforementioned license holders shall submit to the PDEA a monthly summary of the actual usage of the dangerous drug per worker for the month being reported. The summary shall be submitted to the PDEA within ten (10) days of the succeeding month.

Article VI
Retail Sales

SECTION 1. Sale to Individual – An individual who purchases the dangerous drug from a retailer shall be required to present a valid identification card and submit a barangay clearance for the particular purchase, duly issued by the Barangay Chairman of the barangay where the individual presently resides, to the retailer. The barangay clearance shall indicate, among others, the quantity of the dangerous drug to be purchased, the purpose thereof and the Tax Identification Number (TIN) of the individual. It shall be valid only for three (3) days from date of issuance;

SECTION 2. Sale to Industrial User – A holder of an LTPI license may procure the dangerous drug from a retailer by presenting a copy of the license duly certified to by its Chief Executive Officer, Managing Partner, Manager or Proprietor, as the case may be, to the retailer. The original or duplicate copy of the Special Power of Attorney, executed by the appropriate afore-named officers in favor of the individual who shall personally procure and receive the dangerous drug, shall also be presented to the retailer together with a valid identification card of the attorney-in-fact. A clear photocopy of the LTPI license and the Special Power of Attorney shall be submitted to the retailer for each purchase of the dangerous drug. The retailer shall make a notation on the photocopies that the same are the true and exact reproduction of the documents presented;

SECTION 3. Prohibited Sale to Minors - No retailer shall sell or deliver, with or without consideration, to a minor any quantity of the dangerous drug.

Article VII
Record of Dangerous Drug Transactions

SECTION 1. Dangerous Drug Register – All persons granted a license under these Implementing Guidelines shall keep and maintain a dangerous drug register issued by the PDEA. An individual, who shall make an entry in a drug register, shall write and sign his/her name legibly, indicating the date and time of the entry. It shall contain, as may be applicable, the following information:

a. Name, address and license of the foreign supplier, importer, manufacturer, distributor or retailer from whom the dangerous drug has been imported, purchased or acquired;
b. Quantity and brand name of the dangerous drug imported, purchased or acquired;
c. Date of importation, purchase or acquisition;

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d. Name, address and license of the distributor, retailer, industrial end-user or individual purchaser to whom the dangerous drug has been sold or delivered;
e. Quantity and brand name of the dangerous drug sold or delivered;
f. Date of sale or delivery;
g. In case of return, the name of the person to whom the dangerous drug was returned.

SECTION 2. Submission of Report to the PDEA - A certified true copy or computer printout of the aforesaid record covering a period of six months, duly signed by a responsible and authorized signatory of the license holder, shall be submitted to the PDEA, within fifteen (15) days following the last day of June and December of each year.

SECTION 3. Correction of Entry - An individual may, in the presence of a witness, correct a mistake in an entry, provided that the individual making the correction, writes and signs his/her name legibly, indicating the date, in the presence of a witness who shall likewise write and sign his/her name legibly.

SECTION 4. Retention of Register and Documents - Any person required to keep a dangerous drug register shall, subject to any written Direction to the person by the PDEA, retain possession of the register, requisitions and commercial documents relating to entries therein for two (2) years after the date of the last entry in the register. Such records shall be subject anytime to review by the PDEA.

Section 5. Period to Make an Entry - Any person required to keep and maintain a dangerous drug register shall within twenty four (24) hours of any import, export, manufacture, sale, purchase or disposal by that person of the dangerous drug, enter or cause to be entered the required information in the register;

Section 6. False or Misleading Entries - Any person required to keep and maintain a register or other record shall not:

a. make, or cause or permit to be made, an entry in or on it that is, to the knowledge of that person, false or misleading; or
b. cancel, obliterate or alter any entry, except to correct an error.

Section 7. Duty to Notify Loss, Destruction or Discrepancies - Any person required to keep and maintain a register shall upon discovery, submit a written report immediately to the PDEA:

a. the loss or destruction of the register, or of the whole or any part of the contents of the register; or
b. any discrepancy in the register, other than an erroneous entry.

Article VIII
Safekeeping of Dangerous Drug

Section 1. Responsibility of License Holder – All license holders shall keep in a secure and safe storage or depot the dangerous drug under their custody or control. They shall ensure that the safekeeping and handling of the dangerous drug is in accordance within the requirements stated in the Material Safety Data Sheet.

Section 2. Limited Access – All license holders shall take such measures, as the PDEA may direct in writing, to ensure that no unauthorized person has access to the combination, key or other means of access to any secure storage facility or depot containing the dangerous drug.

Article IX
Loss or Theft of Dangerous Drug

Section 1. Duty to Report Loss or Theft – All license holders shall immediately report to the PDEA, in writing, the loss or theft of any quantity of the dangerous drug which are under their custody or control and record relevant

particulars of the loss or theft in the appropriate register.

Article X
Inspection of Records and Premises

Section 1. Inspection for Compliance - A license holder shall, when required by a PDEA regulatory compliance officer, open the dangerous drug register and supporting documents for inspection at any reasonable time and day. During the said inspection, the PDEA officer may require the authorized custodian for a written accounting of the dangerous drug under his/her custody and control for a specified period of time. The license holder shall allow the PDEA officer access to any facility to determine compliance with these Implementing Guidelines.

Article XI
Applicability of Board Regulation No. 3, Series of 2003

Section 1. Suppletory Application – The provisions of Board Regulation No. 3, Series of 2003 shall apply in a suppletory manner.

Article XII
Penalty

Section 1. Penalty for Violation - Any violation of these Implementing Guidelines shall be penalized under Section 32 of R.A. 9165, without prejudice to any other criminal liability arising from the same act punishable under other provisions of R.A. 9165. In case the violation is committed by a partnership, corporation, association or any juridical entity, the partner, president, director, manager, trustee, estate administrator, or officer who consents to or knowingly tolerates its commission, or through negligence failed to avert such violation, shall be held criminally liable.

Article XIII
Separability Clause

Section 1. Judicial Declaration of Partial Invalidity - If for any reason, any section or provision is declared invalid or unconstitutional, the remainder of these Implementing Guidelines shall not be affected by such declaration and shall remain in force and effect.

Article XIV
Effectivity Clause

Section 1. Effectivity - This Regulation shall take effect fifteen (15) days after its publication in two (2) newspapers of general circulation and after its registration with the Office of the National Administrative Register (ONAR), UP Law Center, Quezon City.

Adopted: 21 April 2009

(SGD.) Secretary VICENTE C. SOTTO III
Chairman, Dangerous Drugs Board

Attested:

(SGD.) UNDERSECRETARY EDGAR C. GALVANTE
Secretary of the Board

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