REGULATIONS ON THE CONDUCT OF FACT FINDING ACTIVITIES, GATHERING AND MONITORING OF INFORMATION ON THE RISKS AND ACTIONS ASSOCIATED WITH THE USE OF DEVICES INCLUDING COMPLIANCE M...

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I. RATIONALE / BACKGROUND
The Food and Drug Administration (FDA) through the Center for Device Regulation, Radiation Health and Research (CDRRHR) is the agency in the Department of Health mandated to safeguard public health and regulate devices to ensure its safety and quality pursuant to Republic Act 9711 and its implementing rules and regulations.

Section 3 of Republic Act 9711, or the "Food and Drug Administration (FDA) Act of 2009", states that "the State shall enhance FDA's regulatory capacity and strengthen its capability with regard to the inspection, licensing and monitoring of establishments and the registration and monitoring of health products."

This Administrative Order is being issued as part of the function of the Product Research and Standards Development Division (PRSDD) to establish and maintain the post marketing surveillance system in monitoring health products and incidents of adverse events involving such products in coordination with the Licensing and Registration Division and the Regional Field Offices, including strategizing and developing post market surveillance programs, fact finding activities or gathering and monitoring information on health product risks and actions, and procedures for inspections based on risk and/or other accepted systems.

II. OBJECTIVE

This Administrative Order is being issued to ensure compliance of establishments with the guidelines of the CDRRHR and promote the use of safe, quality and efficacious devices in the Philippines.

III. SCOPE
These guidelines shall apply to all local manufacturers, exporters, importers, distributors, wholesalers and retailers of devices either for domestic commerce, donation or distributed "free of charge" for marketing purposes.

IV. DEFINITION OF TERMS
For purposes of this order, the terms below are defined as follows:

AUTHORIZATION - means 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.

CDRRHR – refers to the Center for Device Regulation, Radiation Health, and Research of the FDA.

COMPLIANCE MONITORING – refers to the activities involved in determining the conformance of establishments with the licensing and registration requirements of the CDRRHR.

DEVICE - means medical devices, radiation devices and health related devices.

- "Medical device" means any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone, or in combinatory for human beings for one or more of the specific purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in intended function by such means.

- "Radiation device" means an electrical or electronic apparatus, emitting any ionizing or non-ionizing electromagnetic or particulate radiation; or any sonic, infrasonic, or ultrasonic wave. It includes ionizing radiation-emitting equipment which is not intentionally designed to produce radioactive materials.

- "Health-related device" means any device not directly used in health care but has been determined by the FDA to adversely affect the health of the people

DISTRIBUTOR/IMPORTER/EXPORTER – means any establishment that imports, exports devices for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.

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, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of devices, including the facilities and installation needed for its activities.

FDA – refers to the Food and Drug Administration.

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.

LGU – refers to the Local Government Units

MANUFACTURER – means an establishment engaged in any and all operations involved in the production of devices including preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.

POSTMARKETING SURVEILLANCE – refers to activities involved in safety, efficacy, and quality monitoring of devices. This shall also include among others adverse events reporting, product safety, update reporting, collection and testing of health products in the market.

PRSDD – refers to the Product Research and Standards Development Division of the CDRRHR

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RETAILER – refers to a person engaged in the business of selling products directly to consumers.

RFO – refers to the Regional Field Office of the FDA.

TEAM – refers to the inspection team, monitoring team or the post-marketing surveillance team composed of two technical staff members.

V. GENERAL GUIDELINES

- The technical staff members of the PRSDD shall conduct fact-finding activities, gathering and monitoring information on the risks and actions associated with the use of devices including compliance monitoring of establishments and post-marketing surveillance of devices nationwide to:

- Determine the compliance of establishments with the licensing and registration requirements of the CDRRHR.

- Continually assess the safety, quality and efficacy of the device already marketed

- Investigate incidents of adverse events relating to the use of a device in coordination with the Licensing and Registration Division and the Regional Field Offices.

- Assess compliance to safety and quality system standards and requirements

- Gather and monitor information on the risks and actions associated with the use of devices.

- Confirm safety and efficacy of the device when adverse event reports suggest that the registration claims are not consistent with the actual use.

- Determine the company's compliance to their after sales obligations.

- The CDRRHR shall require the manufacturers, importers and distributors of devices to mandatorily report adverse events that have resulted, or could result, in serious injury or death.

- The recall of unsafe devices shall be in accordance with the guidelines of the FDA on product recall system.

- The FDA technical staff members shall issue a Notice of Violation against the establishment which violated the existing FDA law, rules and regulations.

- Post-marketing surveillance and monitoring shall be conducted by the PRSDD technical staff members in coordination with the Licensing and Registration Division and the Regional Field Offices.

VI. SPECIFIC GUIDELINES
Monitoring / Post-Marketing Surveillance Inspection Protocol

- All CDRRHR inspectors shall be issued a Department Personnel Order prior to the conduct of the monitoring activity. Upon presentation of this Order together with a valid FDA Identification Card, the CDRRHR team is hereby authorized to:

- enter, at reasonable hours, any factory, warehouse, or establishment of the manufacturers, importers, distributors, retailers or wholesalers of devices introduced for domestic commerce;

- inspect and examine, in a reasonable manner, relevant documents such as certificate of registration, layout / diagram of the device, logbook, records, laboratory test reports and other information related to the device being inspected;

- take pictures, video, audio and copies of documents within the premises, as necessary;

- inspect, to open and examine any receptacle or package that contains devices, as necessary;

- obtain copies of records such as official receipts, sales invoice, distribution records and company logbooks.

- collect samples of devices, parts and accessories if applicable;

- conduct testing of equipment if applicable;

- confiscate prohibited brochures with uncertified / unsubstantiated claims;

- exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

- During inspection, the monitoring team shall inform the establishment of the findings of the inspection. A Notice of Violation shall be issued against the establishment found violating Republic Act 9711. The Notice of Violation and the Inspection Report, together with other relevant evidences obtained during the inspection, shall be endorsed to the Legal Support Services Center of the Food and Drug Administration for appropriate action.

VII. PENAL PROVISIONS

- Prohibited Acts

The following are the Acts prohibited under these guidelines:

- Engage in the manufacture, importation, labeling, distribution, sale and offering for sale of health device/s without the necessary authorizations from the CDRRHR.

- Submission of falsified documents by the establishments.

- Material misrepresentation and/or falsifications of documents for licensing and registration requirements.

- Non-compliance with the standards and requirements on the manufacture, importation, labeling, distribution, retailing and operation.

- Refusal to allow the CDRRHR inspection team to conduct inspection, sampling and testing of devices.

- Administrative Sanctions

The following administrative sanctions shall be imposed by the CDRRHR:

- Any of the prohibited acts mentioned in Section VII (1) hereof shall be a ground for this Center to impose the following sanctions:

- suspension of the registration/license;

- revocation of registration/license;

- seizure and condemnation, destruction and/or appropriate disposition of the unregistered, non-compliant or falsely represented devices;

- Any person or entity that violates any of the provisions of Republic Act No. 9711 otherwise known as the Food and Drug Administration Act of 2009 and its Implementing Rules and Regulations shall be subjected to the corresponding fines and penalties as provided by law.

VIII. TRANSITORY PROVISIONS

The conduct of compliance monitoring and post marketing surveillance of devices function of the PRSDD based

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on this AO shall be turned over to the Regional Field Offices (RFO) upon full implementation of RA 9711 and once the Regional Field Offices are capable of handling the same functions effectively on their own.

IX. SEPARABILITY CLAUSE
In the event that any rule, section, paragraph, sentence, clause or words of these rules and regulations is declared invalid for any reason, the other provisions thereof shall not be affected.

X. REPEALING CLAUSE
All administrative orders, rules and regulations and administrative issuances or parts thereof inconsistent with the provisions of this guideline are hereby repealed or amended accordingly.

XI. EFFECTIVITY
This order shall take effect fifteen (15) days after its publication in an official gazette or in a newspaper of general circulation.

(SGD) JANETTE LORETO-GARIN, MD, MBA-H
Acting Secretary of Health

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