

**[ FDA CIRCULAR NO. 2012-011, September 05, 2012 ]**

**AUTHORITY OF FDA INSPECTORS**

Pursuant to Republic Act 9711 and its implementing rules and regulations, the Food and Drug Administration was tasked to safeguard public health. Article II section c stipulates that the FDA has the function "to analyze, test and/or inspect health products in connection with the implementation of the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances; In line with this Food-Drug Regulation Officer (FDRO) is hereby authorized:

1. To enter, at reasonable hours, any factory, warehouse, or establishment in which drug products are manufactured, processed, packed, or held, for introduction into domestic commerce, or are held after such introduction, or to enter any vehicle used to transport or hold such health products in domestic commerce;
2. To inspect, in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished or unfinished materials, containers, and labeling therein;
3. To take pictures and copies of documents within the premises, as necessary;
4. To inspect, to open and examine any receptacle or package that contains drug products, as necessary;
5. To collect samples of health products. After which, a receipt describing the samples obtained shall be issued to the person-in-charge of the premises/establishment inspected.
6. To implement orders of seizure, to seize and hold in custody any article or articles of any drug, in-vitro diagnostic reagents, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under the FDA Act of 2009, these Rules and Regulations, and as far as applicable, other relevant laws. This will be based on scope of authority unless otherwise assigned.
7. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

All FDA Inspectors shall be issued a certificate of authority which may be presented to the company during the inspection or investigation.

Furthermore, the company must fully cooperate in the inspection and not to obstruct the inspector during inspection process. Violation of such shall be dealt with existing penalties as per Republic Act 9711 and its implementing rules and regulations.

**REPEALING CLAUSE**

All other issuances inconsistent with this Circular are hereby repealed.

**SEPARABILITY CLAUSE**