

16 August 2012

FDA CIRCULAR
No. 2012-014

SUBJECT: DISPOSITION OF FLOOD-AFFECTED HEALTH PRODUCTS

The monsoon rains last 06 – 10 August 2012 and the heavy rainfall brought about by Typhoon Helen, caused extreme flooding including long and massive electrical disruptions in Manila and its surrounding areas and triggered landslides and floods in Luzon. As a result of such flooding, countless factories, warehouses, or establishments in which health products are manufactured, processed, packed, or held for introduction to domestic commerce including drugstores and retail stores have been submerged in flood waters including their respective products thereby adversely affecting or compromising the quality, safety, efficacy, or purity of such health products. For purposes of this Circular, health products refer to food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, or household/ urban hazardous substances and/or a combination of and/or a derivative thereof.

In the interest of public health, safety and welfare, the Department of Health – Food and Drug Administration (FDA) hereby warns establishments as well as the public of health products that were submerged and/ or otherwise affected by the floods that are offered for sale or resale. Thus, this Office hereby enjoins those concerned of their strict compliance to the following:

For consumers

- Do not buy, use, or eat health products or take medicines that have been submerged in flood waters. Those should be thrown in a manner that prevents others from eating, using or taking them.
- Persons who think they may have become ill from eating or taking affected health products are advised to consult their health care providers.

For institutions and food service establishments

- Ensure that affected health products are not served or provided to consumers and to return the affected health products as much as possible to their respective sources.

For drugstores, retail stores, distributors

- Not to sell, offer for sale, or distribute affected health products which are already deemed adulterated.
- Concerned outlets are enjoined to return the affected health products as much as possible to their respective sources.
- Must submit a report to FDA not later than seven (7) working days.

For importers/ manufacturers

- Concerned establishments are enjoined to accept for replacement returned goods.
- Desist from distributing health products which were affected by flood.
- For affected health products, raw materials and packaging materials, those should be disposed in accordance with the proper disposal approved by Department of Environment and Natural Resources (DENR) or other appropriate Office.
- Must inform the FDA at least one week prior the date of destruction for purposes of witnessing and submit inventory of affected health products, raw materials and packaging materials to be destroyed.
- Must submit a post destruction report to FDA not later than seven (7) working days.

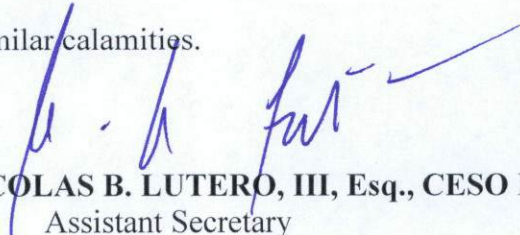
For concerned Divisions and/or Food-Drug Regulation Officers (FDROs)

- Concerned FDROs are instructed to immediately identify the affected establishments and conduct outright monitoring, and if possible, assess and coordinate with affected establishments to prevent distribution of products, the quality or safety of which have been compromised.
- To seize outright any damaged or affected health products for proper destruction at the expense of the establishment.
- To ensure that in areas which were declared under a state of calamity, an automatic freeze in the prices of essential drugs shall be immediately implemented in accordance with Sec. 6 of Republic Act 7581, (otherwise referred as the "Price Act").

Likewise, all concerned are enjoined to report persons or entities dealing in the sale and distribution of affected health products to the DOH-FDA Tel. No. 807-8275, DOH-Centers for Health Development or the Health Office of the Local Government Units for immediate appropriate action.

Any establishment or person caught or found violating this Circular will be administratively and/or criminally penalized accordingly.

This Circular shall apply to future and similar calamities.


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