[FDA CIRCULAR NO. 2013-022, August 23, 2013]

GUIDELINES ON HANDLING CONSUMER COMPLAINTS

I. Rationale:

The need to protect the consumers from violative health products is a state policy and enshrined in our laws, specifically, Republic Act No. 3720, known as the "Food, Drug and Cosmetic Act", as amended by Republic Act No. 9711, known as the "Food and Drug Administration (FDA) Act of 2009", and Republic Act No. 7394 or "The Consumer Act of the Philippines." The FDA is mandated to regulate health products and establishments with the end view of safeguarding public health.

In order to carry out this duty to uphold consumer rights and to strengthen the promotion of consumer welfare, there is a need to streamline the procedures in handling consumer complaints for all the offices of the Food and Drug Administration. Notwithstanding, it must be emphasized that the best interest of the consumer shall be considered in the interpretation and implementation of the provisions of this Circular.

Consumer empowerment does not only mean providing wide choices of consumer products and services but also the establishment of mechanism to effectively address concerns and issues arising from the quality and standards of products and services.

It is for this purpose that the following guidelines for handling consumer complaints are laid down for the information of the public:

II. Scope:

These guidelines shall apply to consumer complaints filed before the FDA for health products and services including advertisements and sales promotions under its jurisdiction not otherwise taken cognizance by the Consumer Arbitrators under Sec. 163 of RA 7394 or other tribunals, quasi-judicial bodies and the regular courts.

III. Guidelines:

Section 1. General Guidelines

1.1 Complainant shall proceed to the concerned FDA Center/Office to file a consumer complaint.

1.1.1 Processed Food Products, & Food Supplements - Center for Food Regulation and Research (CFRR)

1.1.2 Cosmetics, Household/Urban Hazardous Substance and Pesticides - Center for Cosmetic Regulation and Research (CCRR)

1.1.3 Drug, Herbal, Traditional, Veterinary Drug Products, Vaccine and Biological Products - Center for Drug Regulation and Research

(CDRR)

1.1.4 Medical Devices, among others - Center for Device Regulation, Radiation Health and Research (CDRRHR)

1.2 The complainant shall accomplish the Complaint Form (Annex "A" - downloadable thru FDA Website) for walk-in complainants and e-mail complaints. For complaints received through the phone, the concerned FDA Center/Office personnel shall accomplish the complaint form.

1.3 For phone-in complaints, the concerned FDA Center/Office personnel shall properly fill out the details needed and certify that the information set forth in the complaint form faithfully reflects the statements made by the complainant.

1.4 FDA Center/Office representative shall conduct a thorough interview on the matter of the complaint to determine the next appropriate action needed. Information on the complaint must be based on the complainant's personal knowledge and experience. The complainant shall affix his/her signature on the form "CONFORME: (Complainant)."

1.5 The complainant shall attach or submit the necessary supporting documents or piece/s of evidence, such as but not limited to the following: photographs, materials, receipts, medical certificate, and product subject of complaint.

1.6 Complaint product requiring laboratory analysis shall be referred to the Laboratory only after evaluation of Center personnel that the complaint product meets the criteria for acceptance set forth in this guideline. The FDA Center/Office personnel shall accomplish the Laboratory Analysis Referral Form (Annex "B") and shall be acknowledged and signed by the Laboratory personnel.

1.7 The complainant shall be advised of the action that will be taken.

Section 2. Specific Guidelines

2.1 For health products referred for laboratory analysis, the following criteria shall be observed for opened and unopened products submitted for physico/chemical test:

2.2.1 Criteria for Acceptance:

A. Food Product

1. Registered product;
2. Shows any indication of obvious adulteration (i.e. presence of foreign matter) and/or deterioration, if applicable, or has an adverse effect upon ingestion of the sample (with medical certificate, if any);
3. Sample is not yet expired;