



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



23 August 2013

FDA CIRCULAR
NO. 2013-022

SUBJECT: 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 her/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:

2.1.1 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;
4. Sample is in original packaging, properly labeled or accompanied with the empty packaging/container, if transferred;
5. Referral from Acting Consumer Arbitration Officer (ACAO), LSSC or DOH-Legal Service for bottle opening of alcoholic and non-alcoholic beverages

B. Drug Product

1. Registered product;
2. Sample is not yet expired;
3. Properly labeled;
4. Suspected counterfeit or tampered drug or potentially-contaminated product indicated by suspicious odor or unusual color, as certified by CDOR; and
5. Batch-certified in case of antibiotics

C. Cosmetics and Household/Urban Hazardous Substances

1. Notified cosmetic product;
2. Registered household hazardous substances and pesticides;
3. Sample is not yet expired;
4. Suspected presence of adulterants and contaminants, as certified by CDOR; and
5. Adverse reaction occurred despite use of product as directed (to be accompanied by a medical certificate, or as certified by CDOR or CDOR).





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2.1.2. Criteria for rejection for Microbiological Analysis (Food, Drug and Cosmetic Products)

- A. Unregistered and unlabeled products;
- B. Product is already expired;
- C. Presence of filth/visible foreign matter;
- D. Spoiled and/or with foul odor;
- E. Presence of rust, dent and/or bulge on the container;
- F. Improper storage or handling of the product;
- G. Insufficient samples:
 - 1. food – less than 200g or 200mL
 - 2. bottled water – less than 350mL
 - 3. drugs – less than 50g or 50mL
 - 4. cosmetics – less than 3g

Section 3 Types of Consumer Complaints that the FDA Does Not Handle

- 3.1 Restaurant/fast food/hotel/hospital/airline/shipping lines/home-cooked prepared foods and beverages;
- 3.2 Street foods such as “betamax”, “adidas”, “IUD” or isaw, “baticolon”, “kwek kwek”, taho, and the like;
- 3.3 “Tingi-tingi” or “takal-takal” food products sold in public markets/sari-sari stores;
- 3.4 Fresh produce (fruits, vegetables, root crops, poultry, cow’s milk, carabao’s milk, seafood, meat products;
- 3.5 Water from refilling station, and tap water except bottled water;
- 3.6 Rice grains and other grains;
- 3.7 Products suspected in accidental/Intentional poisoning;
- 3.8 Dangerous drugs, as defined by law;
- 3.9 Agricultural pesticides and fertilizers;
- 3.10 Products used in medical malpractice;
- 3.11 Products subject to senior citizen discount;





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- 3.12 Products involved in violation of Price Act, except for drug products covered by the Maximum Drug Retail Price (MDRP) and Government Mediated Access Price (GMAP);
- 3.13 Products subject of complaint on trade of a company against another company, except on cases involving health product being counterfeited; and
- 3.14 All processed canned and meat products.

Section 4 Additional Guidelines

The public is reminded to be vigilant in buying processed food, drugs, cosmetics and other health products to ensure their safety. Consumers are encouraged to observe the following recommendations:

- 4.1. Buy health products from licensed and legitimate establishments.
- 4.2. Be vigilant and buy only registered health products.
- 4.3. Do not buy products with foreign labels or without English or Filipino translations.
- 4.4. Always check the label for the expiry date or best before date.
- 4.5. Avoid buying health product with dented or deformed packaging.
- 4.6. Check www.fda.gov.ph website for verification of registered health products.
- 4.7. You may also report on-line at www.fda.gov.ph: tab "eReport" or please email directly at report@fda.gov.ph.
- 4.8. For complaints involving Adverse Drug Reaction (ADR), please accomplish on-line ADR Form at www.fda.gov.ph: tab "ADR Report".
- 4.9. For more information and clarification, please email info@fda.gov.ph.

This Circular shall take effect immediately.


KENNETH Y. HARTIGAN-GO, MD
Acting Director General

