Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

PRODUCT COMPLAINT FORM
ANNEX A

Date of Filing/ Araw ng Pagtala DD/MM/YYYY
Center Concern: (Select One) Tracking No: _____
to be accomplished by FDA personnel

B. PERSONAL DATA/ SARILING DATOS

Name of the Complainant / Pangalan ng Nagrereklamo _____
Last name, First name M.I.

Home Address / Tirahan _____

Telephone/ Telepono _____ Mobile /Cellphone No. _____ Email _____

C. PRODUCT BEING COMPLAINED/ IMPORMASYON NG PRODUKTONG INIREREKLAMO

Product Category/ Kategorya ng Produkto: Others _____

Product Identity/ Pagkakakilanlan ng Produkto: _____
(Brand Name/Generic Name/ Product Name)/ (Tatak at Pangalan ng Produkto)

Product Description/ Diskripsyon ng Produkto: _____
*include the following for FOOD and COSMETIC PRODUCTS: Net weight/packaging; DRUG PRODUCTS: Dosage Form/ Dosage Strength

Product Code: (Select One) _____

Date Marking: (Select One) _____ (Select One) _____

Manufacturer/Address : _____

Importer/Address : _____

Distributor/Address : _____

Trader/Address : _____

Others : (Select One) _____

D. NATURE AND DETAILS OF COMPLAINT/ DETALYE NG REKLAMO:

Date Purchased/ Araw na Binili: DD/MM/YYYY Date of Consumption of Complained Product/ Araw na ginamit o kinain ng inirereklamong produkto: DD/MM/YYYY

Place Bought/ Tindahan kung saan binili: _____

Request(s): _____

History/Paglalahad ng Pangyayari:

_____
(Printed Name over Signature /Lagda sa ibabaw ng Pangalan)
FDA Center Representative (Interviewer)

Information Checked and Verified by: _____
Conforme:
(Printed Name over Signature/ Lagda sa ibabaw ng Pangalan)
Complainant/Authorized Representative

to be accomplished by FDA personnel

REGISTRATION STATUS: Registered: (Select One) If yes- Please indicate Registration No: _____
Valid: (Select One) If yes- Valid until _____

LICENSCE TO OPERATE STATUS: with LTO: (Select One) If yes- Please indicate Registration No: _____
Valid: Not Applicable If yes- Valid until _____

Evidence Presented/Ebidensyang Ipinakita (if applicable/ kung mayroon man): _____

Amount/Number of Submitted Samples: _____

Package Type:
- ☐ Can/Retortable Pouch
- ☐ Plastic Bottle
- ☐ Glass Bottle
- ☐ Flexible Plastic Container/Bag
- ☐ Tetra Pack
- ☐ Doy Pack
- ☐ Rigid Plastic Container
- ☐ Polyfoil with Multivac/Cryovac
- ☐ Polyfoil bag
- ☐ Polyethylene bag
- ☐ Alu, Poly, Tray Packing
- ☐ Others _____
- ☐ Blister Pack
- ☐ Foil Strip
- ☐ Foil Pack

Container Condition:
- ☐ Original Container Unopened without Seal
- ☐ Original Container Unopened with Seal Intact
- ☐ Original Container Opened/Seal Broken or Tampered
- ☐ Not in Original Container, please describe container

Findings/ Suggestions/ Comments:

Action Taken: (Select One) _____ **Approved by:** _____
(Printed Name over Signature)

FORM TITLE:
ANNEX B **REQUEST FOR ANALYSIS**

FORM NO.: SOP-2.4-01.ANX1
REVISION: 01
EFFECTIVITY: 02 JANUARY 2013

Date: _____

Product Category:
- ☐ Pharmaceuticals
- ☐ Food
- ☐ Cosmetics
- ☐ HHS
- ☐ Medical Devices
- ☐ Others: _____

Product Source:
- ☐ Government Delivery
- ☐ Collected
- ☐ Complaint (kindly accomplish page 2 of this form)
- ☐ Others _____

REGION: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 ☐11 ☐12 ☐NCR ☐CAR ☐ARMM ☐CARAGA

LABORATORY NUMBER:

☐ **Received** ☐ **Rejected**

Signature over Printed Name

Reason (if rejected)

Date:

PRODUCT INFORMATION

Test Items

(Generic Name/ INN/ Product Name)

(Brand Name)

Dosage Strength/Label Claim/ Amount of Active or Substance	**Dosage Form/ Category or Type/ Physical Form** (for foods)
Batch Number	**Lot Number**
Date of Manufacture	**Expiration Date/ Best Before Date**
Registration Number	**Number of Submitted Samples** (# of units in packaging eg. Blister, foil strip, no. of units per box or bottle)

Packaging Type
- ☐ Foil Strip
- ☐ Foil Pack
- ☐ Can/Retortable Pouch
- ☐ Plastic bottle
- ☐ Tetra Pack
- ☐ Blister Pack
- ☐ Glass bottle
- ☐ Doy Pack
- ☐ Rigid Plastic Container
- ☐ Flexible Plastic Container/ Bag
- ☐ Others _____

Container Condition
- ☐ Original Container unopened without seal
- ☐ Original Container unopened with seal intact
- ☐ Original Container opened/ seal broken or tampered
- ☐ Not in original container *(Please describe container)* _____

Manufacturer	**Address**
Distributor/Address	**Importer/Address**
Trader/Address	**Repacker/Address**

Purpose of Collection

Analysis Requested

- ☐ Visual Exam
- ☐ Chemical
- ☐ pH
- ☐ Content Uniformity/ Weight Variation
- ☐ Biological Test (LAL/Pyrogen/Safety)
- ☐ Tablet Hardness
- ☐ Dissolution
- ☐ Sterility
- ☐ Microbiological Exam/ Microbial Limits
  - ☐ SPC/APC
  - ☐ Coliform count
  - ☐ *Listeria monocytogenesis*
  - ☐ S. aureus
  - ☐ E. coli
  - ☐ Salmonella
  - ☐ Mold and Yeast count
  - ☐ Commercial sterility
- ☐ Conformity to Label Claim (include Assay/Potency)
  - ☐ single component
  - ☐ multi-component
- ☐ Additives
- ☐ Contaminants
- ☐ Micronutrient (pls. specify the added fortificant)
  - Vitamin A: ☐ Retinol ☐ Palmitate ☐ Acetate
  - Iron: ☐ Fe ☐ $FeSO_4$ ☐ $C_4H_2FeO_4$
- ☐ Other, pls. specify _____

PRODUCT SOURCE

Name of Establishment

Address

Date Product was Bought/ Collected (indicate collection receipt number)

Date When Product was opened (For Previously Opened Product)

Sampling Plan

Environmental Conditioning during Sampling: (includes temperature °C, RH, explain all necessary condition: storage, abnormalities, etc.; use separate sheet if necessary)

Other Pertinent Product Information (for consumer complaint samples)

REQUESTING PARTY

Name	**Agency/ Organization**
Designation	**Address**
Signature	**Telephone No./ Fax No.**

NOTE:
1. *Please fill-out the form completely in **A4 size** paper and write all entries legibly.*
2. *This form shall be used only when requesting for laboratory analysis of a product. All requests for verification if a product is registered or not shall be addressed to the **PRODUCT SERVICES DIVISION (PSD).***
3. *Use/ Print page 2 of this form for Consumer Complaint Samples for laboratory analysis of a product.*

FORM TITLE.

REQUEST FOR ANALYSIS

FORM NO.: SOP-2.4-01.ANX1
REVISION: 01
EFFECTIVITY:
02 JANUARY 2013

CONSUMER COMPLAINT SAMPLE INFORMATION

1) SAMPLES

1.1 Amount of Samples Submitted (number x volume / weight)

_____

1.2 Is the sample submitted part of the consumed food suspected to have caused alleged illness/injury suffered by the complainant/s?

- ☐ YES
- ☐ NO, but from same lot code
- ☐ NO, purchased from the same outlet/received from same person/entity
- ☐ Others, *please specify*

_____

_____

1.3 Appropriate storage condition

- ☐ Ambient/ Room Temperature
- ☐ Requires refrigeration
- ☐ Frozen

1.4 Storage before submitting for analysis to FDA

_____

_____

_____

_____

2) NATURE OF COMPLAINT

Brief description of circumstances leading to complaint, including to but not limited to those indicated below is important to determine the appropriate laboratory examination

- ☐ Bottle beverages (alcohol and non-alcoholic) with visible foreign matter
- ☐ Opened can/ foil pack/ tetra pack/ with spilled content due to pinholes/ defective packaging materials
- ☐ Opened canned food products with foreign matters
- ☐ Other food material (i.e. bread) in plastic packaging
- ☐ Others, *please specify*

_____

For Test items requiring Micro analysis, kindly fill-up 2.1 to 2.8

2.1 Date/time of Consumption of Complained Product

2.2 No. of Days/ Hours Between Consumption and Purchase/ Acquisition of Complained Product

2.3 No. of Person who Consumed the Product

2.4 Description of Symptoms Manifested (e.g. vomiting, diarrhea, etc.)

2.5 Date/ Time of Onset of Symptoms

2.6 No. of Persons Affected with Similar Symptoms

2.7 Is/are the person/s affected was/were examined by a physician or confined has/have/ been in hospital

- ☐ NO
- ☐ YES *(please attach/ submit copy of medical certificate)*

Medical Certificate attached ☐ NO ☐ YES

2.8 Additional Information *(use separate sheet if necessary)*

_____

_____

_____

_____

3) COMPLAINANT

Name	**Agency/ Organization**
Designation	**Address**
Signature	**Telephone No./ Fax No.**

FOR LABORATORY SERVICES DIVISION USE ONLY

Describe condition upon receipt and how the product was transported to FDA (particularly to product requiring refrigeration or frozen storage)

_____

_____

_____

_____

_____

_____

NOTE:

1. *Please fill-out the form completely in **A4 size** paper and write all entries legibly.*
2. *This form shall be used only when requesting for laboratory analysis of a product. All requests for verification if a product is registered or not shall be addressed to the **PRODUCT SERVICES DIVISION (PSD).***
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