Taiwan Cosmetic Management Policies and Achievements

FDA

CONTENTS

Safety

Regulations

Quality Control

What is Cosmetic Product?

“Cosmetics” means products applied externally to the human body, teeth, or oral cavity mucous membranes, and used to moisturize hair and skin, stimulate the sense of smell, improve body odors, change appearance, or cleanse the body. However, this is not applicable to those that are regarded as drugs in accordance with other laws or regulations.

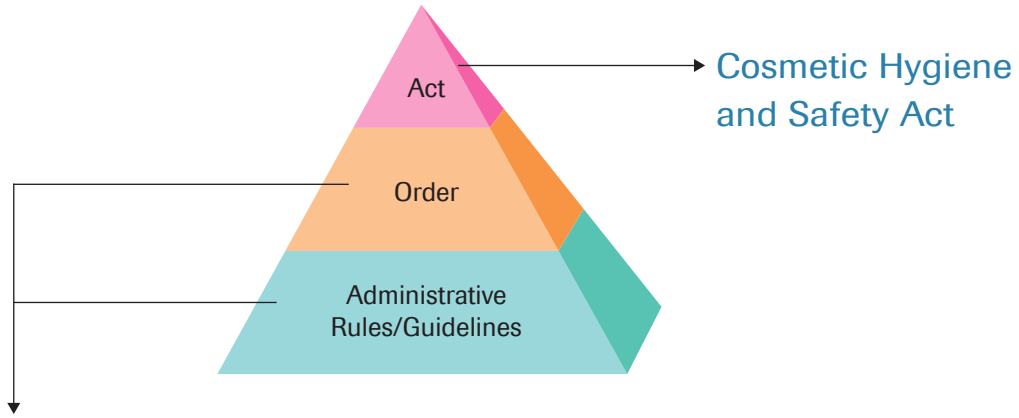
Specific Purpose Cosmetics

Specific purpose cosmetics: refers to cosmetics that contain sunscreen, as well as hair-dyeing, permanent waving, antiperspirant, deodorant, tooth-whitening or other purposes as specified in the List of Specific Purpose Ingredients in Cosmetic Products.

These Regulations have been translated into English according to the original Chinese version.

If there is any inconsistency or ambiguity between these two versions, the Chinese version shall prevail.

Introduction to Cosmetic Regulations



◆Enforcement Rule

- Enforcement Rules of Cosmetic Hygiene and Safety Act

◆Regulation

- Regulations for Issuance and Management of the Cosmetics Certificates
- Regulations for Issuance of License of Specific Purpose Cosmetics
- Regulation for Authorizing the Applications of Import of Non-licensed Specific Purpose Cosmetics
- Regulations for the Inspection and Examination of Imported Cosmetics
- Regulations Governing the Source and the Flow Data of Cosmetic Products
- Regulations for Qualifications and Training of Cosmetics Professional Technicians
- Regulations for Cosmetic Product Information File Management
- Regulations Governing Notification of Cosmetic Products
- Regulations for Reporting Cosmetics Serious Adverse Effects and Hazards to Hygiene and Safety
- Regulations on Cosmetic Hygiene and Safety Violation Report and Reward
- Regulations Governing the Application of Animal Testing for the Safety Assessment of Cosmetics or Cosmetic Ingredients
- Regulations for Cosmetics Recall
- Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions
- Cosmetics Good Manufacturing Practice (GMP) Regulations
- Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical efficacy of Cosmetic Products

◆Standard

- Establishment Standards for Cosmetics Manufactory
- Standards of Administrative Fees for Cosmetics

◆Announcement

- Labeling Requirements for Cosmetic Packaging, Containers, Labels or Directions
- Other related announcements

Cosmetic relevant regulation

TFDA website(www.fda.gov.tw) > Cosmetic > Law & Regulations

Cosmetic Safety Management Structure

Pre-market

Importers shall confirm that the imported cosmetics comply with Cosmetics GMP Regulations, and adopt the cosmetic ingredient use and hygiene standards

Import

Factory set up

Product development

Manufacture (Made in Taiwan)

Selling, Advertisement

Use

Factory registration

Comply with Establishment Standards for Cosmetics Manufactory

Comply with cosmetic ingredient use and hygiene standards

Pharmacists or cosmetics professional technicians supervise the manufacturing of cosmetics

Comply with Cosmetics GMP Regulations (Implemented by phases from 2024.7.1)

Establish PIF (Implemented by phases from 2024.7.1)

Registration (Invalid from 2024.7.1)

Complete of labeling in Chinese

Complete of product notification (Implemented by phases from 2021.7.1)

Post-market

Comply with Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical efficacy of Cosmetic Products

Record the product supply source and flow data

Establish the operating procedure of cosmetics recall

Defective products on market should cooperate with recall procedures

Report events of cosmetic adverse effects

Monitor international cosmetic warnings

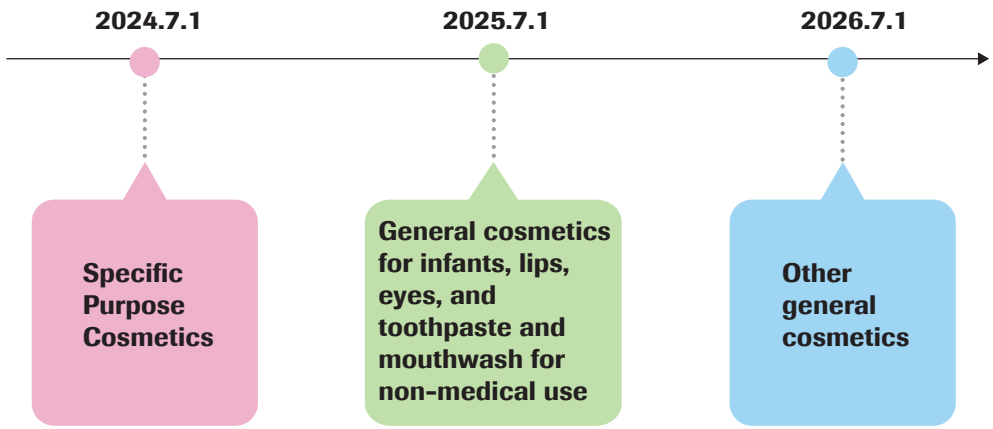
GMP:Good Manufacturing Practice
PIF:Product Information File

Cosmetic Manufacturing Facilities Management

◆Cosmetic Manufactory Management

- Domestic cosmetics manufactory shall complete the factory registration, and licensed pharmacists or cosmetics professional technicians shall be hired and stationed at the factory to supervise the dispensation and manufacturing of cosmetics.
- Domestic cosmetics manufactory shall comply with the Establishment Standards for Cosmetics Manufactory.
- When dealing with specific purpose cosmetics, the registration must be completed prior to manufacturing, and no manufacturing shall be allowed until a license is approved and issued.
- Starting from July 1, 2024, for cosmetics categories that are specified by the central competent authority as per public announcement, their domestic and overseas manufacturing facilities for cosmetics shall comply with cosmetics GMP Regulations.
  The facilities are subject to on-site inspection by the central competent authority.

◆Specified Cosmetic Categories Shall Comply with Cosmetics GMP Regulations and the effective date.



◆ISO 22716:Cosmetics-Good manufacturing practices (GMP)-Guidelines on good manufacturing practices

The Cosmetics Good Manufacturing Practices Regulations are formulated in reference to the ISO 22716: Cosmetics-Good manufacturing practices (GMP)-Guidelines on good manufacturing practices issued by International Organization Standardization.

Product Hygiene and Safety Standards

- "Cosmetics ingredient" means a single chemical entity or mixture contained in cosmetics.
- Cosmetics shall not contain mercury, lead, or other ingredients banned for use as per public announcement of the central competent authority. However, this restriction does not apply to residual traces contained therein that are inevitable due to contemporary technical or professional standards, provided that such traces pose no hazard to human health.
- The central competent authority may restrict the use of cosmetics ingredients to prevent and avoid causing allergies, irritations, depigmentation, and conditions that pose a hazard to human health.

Cosmetic Ingredient Use and Hygiene Standards

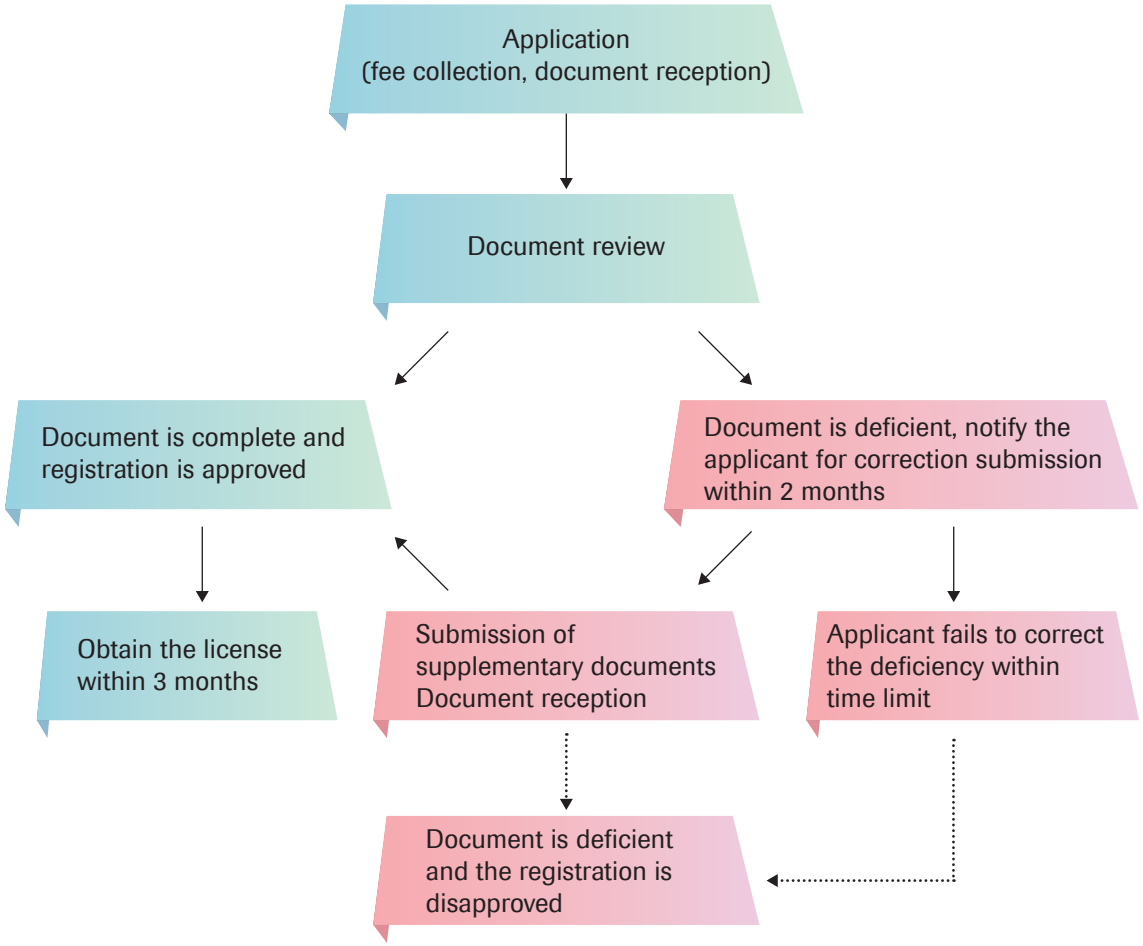
Ingredients prohibited in cosmetic products (negative list)	**Ingredients restricted in cosmetic products (with reference to European, American, and Japanese standards)**	**Other**
List of ingredients prohibited in cosmetic products	• List of Specific Purpose Ingredients in Cosmetic Products • List of Colorants in Cosmetic Products • List of Preservatives in Cosmetic Products	• List of Ingredients Restricted in Cosmetic Products • List of Microorganisms Limits in Cosmetic Products • List of Antibacterial Ingredients Allowed in Cosmetic Products

[web]

Regulations governing the management of prohibited and restricted cosmetic ingredients
https://consumer.fda.gov.tw/LAW/Cosmetic1.aspx?nodeID=1068&rand=656806769

Regulations for the Registration of Specific Purpose Cosmetics (Invalid from 2024.7.1)

Importer / Manufacturer



Notes

- Prepare the documents for registration in accordance with the Regulations for Issuance of License of Specific Purpose Cosmetics. If an application for the modification is required, the cosmetics business that has obtained the license of specific purpose cosmetics may check Documents Required for Applying for Modification of Registrations and Licenses for Specific Purpose Cosmetics to apply for the modification.
- For a change that satisfies the Particulars of Specific Purpose Cosmetics that May Be Voluntarily Modified, the cosmetics business may change the product package at its discretion without application for the package modification of specific purpose cosmetics.

Import of Non-licensed Specific Purpose Cosmetics

- For products imported by cosmetics businesses for registration or by cosmetics businesses or institutions for use in research and trial, the application shall be managed in accordance with the Regulations for Authorizing the Applications of Import of Non-licensed Specific Purpose Cosmetics.
- To import specific purpose cosmetics for personal use, it could be exempt from registration that shall be managed in accordance with the Limited Numbers on Registration of Exemptions from the Inspection of Imported Specific Purpose Cosmetics for Personal Use.

Preparation for Introducing on the Market

Importer / Manufacturer and Seller

- The company registration (or business registration) shall be completed.
- In the case of specific purpose cosmetics, the registration shall be completed, and the license for specific purpose cosmetics shall be acquired prior to manufacturing (domestic production) or importation.
- The cosmetics business shall confirm that the product ingredients comply with the regulations of cosmetic ingredient and assure the safety and stability of products.
- Cosmetics manufacturers or importers shall complete the cosmetic product notification*1 and product information file (PIF) *2 prior to the supply, sale, giveaway, public display, or consumer trial offer of cosmetics in Taiwan.
- Cosmetics manufacturers, importers or sellers shall record and establish data on supply sources and destination of products. *3
- Cosmetics manufacturers or importers shall establish the operating procedure of cosmetics recall. *4
- Complete Chinese label of product before introducing on the market.

*1 To be implemented in phases starting July 1, 2021.

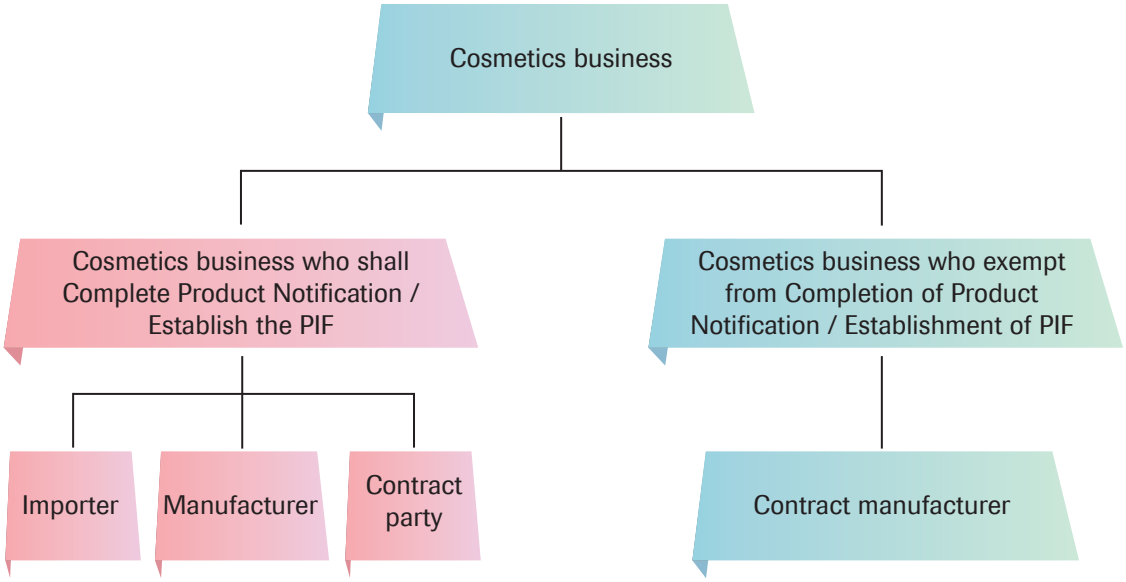
*2 To be implemented in phases starting July 1, 2024.

*3 The provision shall not apply to data on products directly sold to consumers.

*4 The seller shall cooperate with importers/manufacturers for recall.

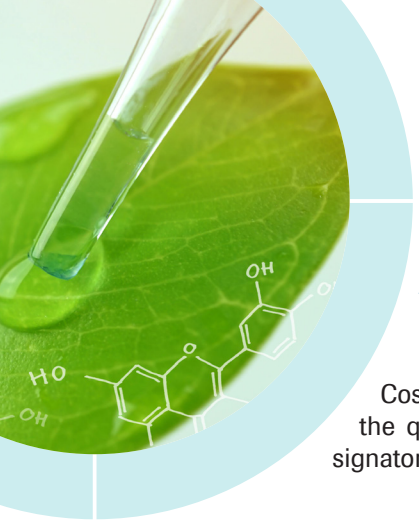
Notification of Cosmetic Products and Cosmetic Product Information File (PIF)

◆ Cosmetics Business Who Shall Complete Product Notification / Establish the PIF



◆ Data that should be notified

1. Notification number of products.
2. Chinese and English names of products provided that no need to notify the English name of domestic products.
3. Category and usage of products.
4. Type of products. Model number and color code for series products.
5. Dosage of products.
6. Precautions of products.
7. Names, addresses and telephone numbers of manufacturers or importers of products.
8. Names, addresses and nationalities of the premises where products manufactured and other criteria conforming to cosmetics Good Manufacturing Practice (GMP).
9. Full components of products. Weight or capacity percentage identifying its content inclusion if limitation of usage set forth by the central competent authorities.
10. Other relevant descriptions.
    The aforesaid data notify shall be made in Chinese, English, numbers or international symbols.



◆Data that should be established for product information file

Cosmetic product information file (PIF) refers to documents regarding the quality, safety, and functions of cosmetics that have been confirmed by signatory for the safety report via assessment as appropriate.

The content is generally categorized as follows:

1. Basic information of product on the market.
2. Quality information.
3. Supporting information of the functional assessments.
4. Safety assessment information.

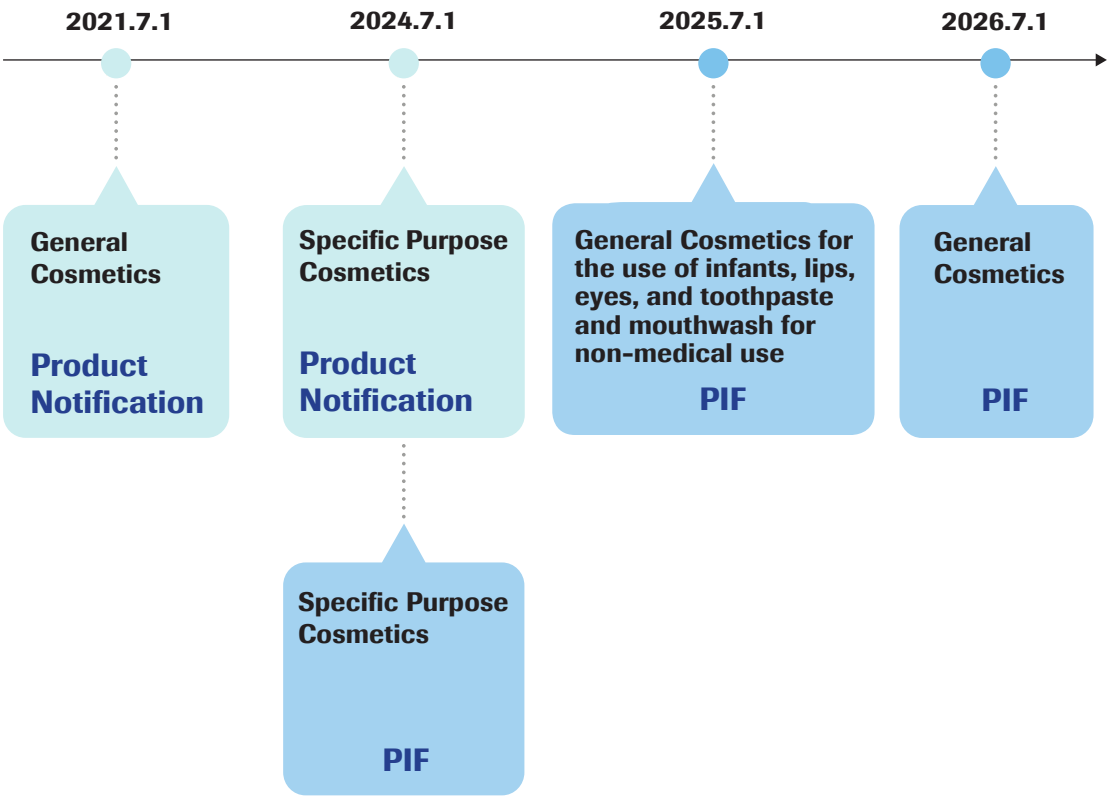
- The cosmetic product information file may be stored by written records or the means of electronic data storage media. If the original information of the file is established in the language other than Chinese or English, the Chinese or English translation shall be attached.
- The file shall be kept for at least five years from the next day of the date of the product lastly available in the market.

◆Qualification of Signatory for the Safety Report

1. A person who graduated from department of medicine, department of pharmacy, toxicology, cosmetic and other related departments or graduate schools at the domestic university or the foreign university which complies with Regulations Governing the Assessment and Recognition of Foreign Academic Records by Institutions of Higher Education, and has taken cosmetic safety evaluation training courses which are provided by domestic or foreign university, or by central competent authority.
2. The signatory for the safety report of product information file shall take at least eight hours relevant courses yearly.
3. The countries (regions) or areas which have signed the cooperation agreements of the signatory for the safety report of product information file with R.O.C (Taiwan).

* An employee or external professional consultant that meets the preceding qualifications may serve as a signatory for the safety report.

◆ The cosmetic categories that shall been notified, established PIF and the effective date



Label and Advertisement Regulations

Importer / Manufacturer and Seller

◆ Required Items to be Labeled in Chinese [*5]

1. Product name.
2. Function.
3. Usage and storage instructions.
4. Net weight, volume, or amount.
5. Full ingredient names. For specific purpose cosmetics, the content of specific purpose ingredients contained therein shall be labeled separately. [*6]
6. Precautions for use.
7. Name, address, and telephone number of manufacturer or importer; country of origin of imported product.
8. Manufacturing date and shelf life, or manufacturing date and expiration date, or shelf life and expiration date.
9. Lot number.
10. Other information required to be labeled as per public announcement of the central competent authority.

"Label" means a marking object used to bear words, graphics, or symbols for affixation on the container or package of a cosmetic.

*5 The information to be labeled shall be provided in Chinese or internationally common symbols.

*6 Full ingredient names may be labeled in English. For specific purpose cosmetics, the content of specific purpose ingredients contained therein shall be labeled separately.

The container should be labled the product name at least in either Chinese or foreign language.

“Leaflet” means an instruction sheet accompanying a cosmetic.

◆Regulations for the terms alleged in the label, promotion and advertisement (including the description, pattern, product name, symbol, image, sound, etc.)

- The contents of the labeling, promotion, and advertisement of cosmetics shall not be deceptive or exaggerated, e.g., losing weight, fat reduction, immunization enhancement, breast enlargement, pharmaceutical grade, etc.
- Cosmetics shall not be so labeled, promoted, or advertised as having medical efficacy, e.g., chemical hair removal, hair off, sterilization, anti-inflammatory, hair restore etc.
- Content shall be judged based on comprehensive performance and compliance with Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical efficacy of Cosmetic Products.

⚠ Sellers of cosmetics shall not alter or modify the labels, leaflets, outer packaging, or containers of cosmetics for sale.

Market Monitoring and Safety Reporting

Market Audit

The competent authority shall manage the cosmetic audit plan, inspection on test basis, and periodic online monitoring. Where a product defect is found, the competent authority will notify the cosmetics business for improvement by setting a deadline or recalling the product on the shelf.

SAE & Hazards Reporting

Where severe adverse effects (SAE) caused by the product to the human body are found or health and safety may be endangered, the cosmetics business shall report the case via the network system [*7] within 15 days, and the competent authority will notify the cosmetics business to recall the product on the shelf when the product is considered defective.

The public may report via such system when the preceding condition is found.

● Scope of Reporting for Adverse Effects of Cosmetics

Label Issues	· Incomplete label · No label · False label (including an alleged medical effect for the cosmetic)
Abnormal Result of Use	· Doubt of problem ingredient or suspicious of containing drug or banned ingredient for cosmetics
Abnormal Appearance	· Color · Odor · Clotting · Abnormally separated · Foreign object
Packaging Defect	· Extravasations · Broken · Non-functional
Expiry	· Past the expiration date
Adverse Effects	· Hazardous, non-intentional individual effect caused by using cosmetic in a normal or reasonable way
Others	· Problems other than the preceding items

*7 **Network System**
https://qms.fda.gov.tw/tcbw/

Reporting

In case of violation, reporters may file reports in oral or written statements, by email or others, and the competent authority will launch an investigation and manage the case pursuant to laws. *8

International Warning

International cosmetic related safety warnings*9 shall be monitored periodically to determine whether a product circulating in the country has the problems described in an international warning. If so, recall the products on shelf. Meanwhile, certain cosmetics categories or items shall be announced in accordance with the Regulations for the Inspection and Examination of Imported Cosmetics, and may only be imported after sampling checks and sampling tests show compliance.

*8 **Regulations on Cosmetic Hygiene and Safety Violation Report and Reward**
In general, the reporter may receive at least 5% of the fine paid for reporting a cosmetic violation. However, if the reporter is employee at a service or resigned who reported the violating employer, the reward may be raised as certain conditions are satisfied.

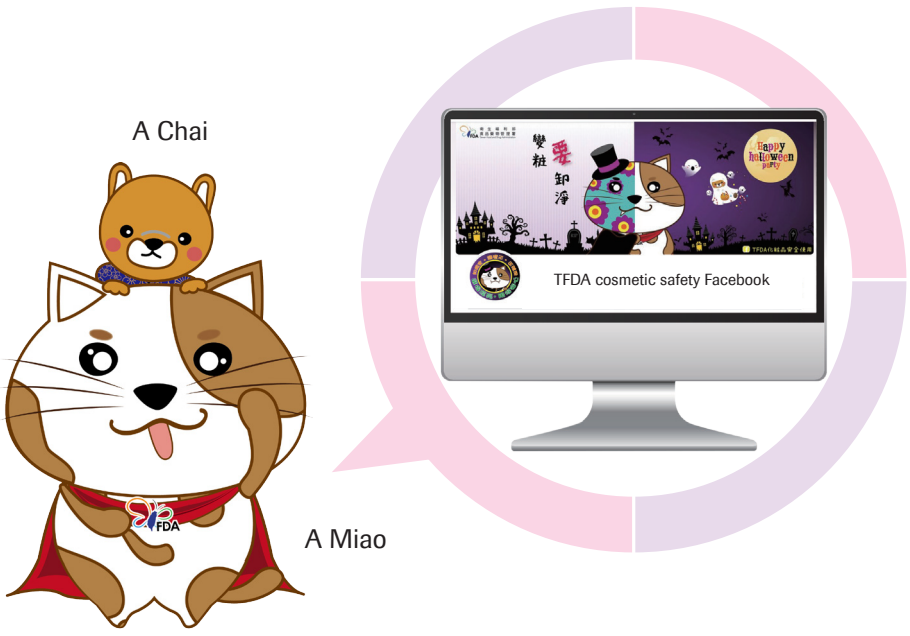
*9 **Warning on International Cosmetic Consumption**
https://consumer.fda.gov.tw/Light/List.aspx?code=2010&nodeID=32

International Cooperation

- The international symposium and workshop on cosmetic regulation have been organized continuously since 2010, and the experts of the EU, the US, Japan, and other such countries are invited to participate.
- Participate in ICCR and its working groups aggressively since 2016.

Reinforce the Risk Communication with Public Enhance Self-protection for Cosmetic Purchase

- To properly pass cosmetic safety and use information and enhance self-protection of consumers as selecting cosmetics, the Taiwan Food and Drug Administration of the Ministry of Health and Welfare shall promote the idea of “3 steps to ensure the safe use of cosmetics for smart and brilliant purchases –regulations knowledge, label identification, and correct use”.
- Enforcement measures
  - Promote character image.
  - Production of all kinds of printed literature and materials such as health education manuals, short films, leaflets, hands draw and graphic novels.
  - Various promotional activities.
  - Establish “TFDA cosmetic safety use” Facebook fan club.



Summary

Cosmetic Hygiene and Safety Act has been implemented since July 1, 2019 to maintain the hygiene and safety of cosmetics in order to safeguard national health from source management to post market auditing.

Reinforce source management

- **Product information file (PIF):** Carry out the cosmetics businesses self-verification, product quality, and safety and function assessment.
- **Cosmetics GMP:** Established an excellent quality management system will help the industry expand export sales and improve the protection of consumers' health and safety.
- **Border inspection and examination:** In the significant danger event of international cosmetic, the border management of cosmetics may be reinforced to protect the health and safety of consumers.

Complete post market management

- **Product notification:** Enhance the autonomous management ability of businesses and the transparency of product information. By publishing the basic information for customers to openly review, compare and purchase products. That can help promote the legal imagination of products.
- **Product direct supply source and destination data establishment:** Ensure that the product flow information can be seized in case of an emergency.
- **SAE & Hazards reporting:** Enhance the management responsibility of cosmetics businesses. For unexpected adverse effects of cosmetics, cosmetics business should proactive notify the competent authority, clarify the source of the problem and reinforce the ability of dealing with emergency.
- **Whistle blowing terms:** Encourage all nationals to monitor illegal events and publish violation information in order to ensure the health and rights of consumers.
- **Recall and Withdrawal:** The competent authority may order the cosmetics business to recall and withdraw violating products from the market within time limit.

Organization of the Taiwan Food and Drug Administration

衛生福利部
食品藥物管理署
FDA Taiwan Food and Drug Administration

Add:No.161-2, Kunyang St, Nagang District,
Taipei City 115-61, Taiwan(R.O.C)
Tel:+886-2-27878000
Web:www.fda.gov.tw