Overview of Cosmetics and OTC (Drug) Regulations and Import Procedure into U.S.A.

미국의 화장품 및 일반의약품 제도 및 수입절차 개요

Prepared

for

Host: Ministry of Food and Drug Safety(MFDS)

Organizer: Korea Cosmetic Association(KCA)

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October 30, 2020

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United States Census Bureau

U.S. and World Population Clock

The United States	The World
미국 인구 3억3천만명	전세계 인구 77억명

Oct 28, 2020 15:43 UTC (+4)

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U.S. Population

330,512,340

World Population

7,693,741,01

Components of Population Change

15:43:34 UTC

- One birth every **8 seconds**
- One death every **12 seconds**
- One international migrant (net) every **47 seconds**
- Net gain of one person every **18 seconds**

TOP 10 MOST POPULOUS COUNTRIES (July 1, 2020)

1. China	1,394,015,977	6. Nigeria	214,028,302
2. India	1,326,093,247	7. Brazil	211,715,973
3. United States	329,877,505	8. Bangladesh	162,650,853
4. Indonesia	267,026,366	9. Russia	141,722,205
5. Pakistan	233,500,636	10. Mexico	128,649,565

1. Current U.S. Market & Trends 미국 시장, 동향

Five Generations Working Side by Side in 2020

TRADITIONALISTS	BOOMERS	GEN X	MILLENNIAL	GEN 2020
Born 1900-1945	Born 1946-1964	Born 1965-1976	Born 1977-1997	After 1997
Great Depression World War II Disciplined Workplace Loyalty Move to the 'Burbs' Vaccines	Vietnam, Moon Landing Civil/Women's Rights Experimental Innovators Hard Working Personal Computer	Fall of Berlin Wall Gulf War Independent Free Agents Internet, MTV, AIDS Mobile Phone	9/11 Attacks Community Service Immediacy Confident, Diversity Social Everything Google, Facebook	Age 15 and Younger Optimistic High Expectations Apps Social Games Tablet Devices
25M (8%)	**70M (21%)**	**65M (20%)**	**83M (25%)**	**85M (26%)**

1. Current U.S. Market & Trends 미국 시장, 동향

Do-it-yourself and self-care beauty products are growing quickly in the United States.

DIY & Self-Care 뷰티 제품 급성장!

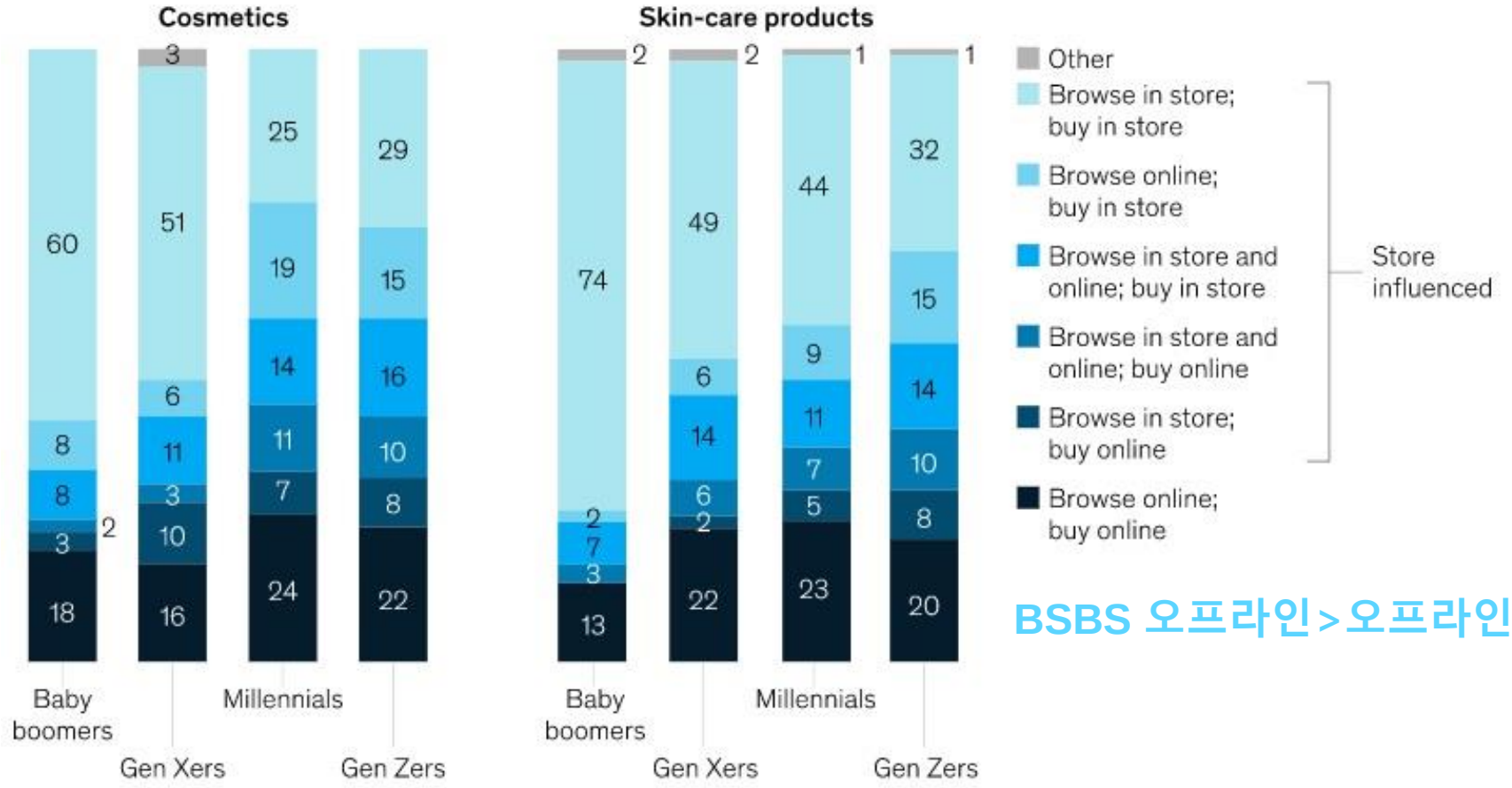
Do-it-yourself and self-care products

Beauty-product category	Estimated year-to-date sales, $ million	Average price, $	Year-over-year change, 2019–20, 4 weeks ending April 11: Retail sales, %	Average price, %	Retail sales, $ million
Body wash, soap, and lotion	321	14.10	65	–11	44
Nail care	123	15.02	218	16	37
Hair care	540	18.43	27	–12	33
Men's grooming	240	25.44	56	6	28
Skin care	540	18.17	20	–14	27
Hair coloring	58	13.64	172	–3	17
Women's hair removal	74	16.15	53	–14	9
Eye makeup	82	12.30	5	–12	1
Face makeup	77	13.87	–3	–21	–1
Lip care and color	55	8.97	–15	–28	–2
Beauty tools, devices, and accessories	316	16.60	–7	–15	–6
Total beauty products[1]	2,632	N/A	28	N/A	172

Note: From Amazon results.
[1]Includes fragrances and sun-care and tanning products.
Source: Stackline

1. Current U.S. Market & Trends 미국 시장, 동향

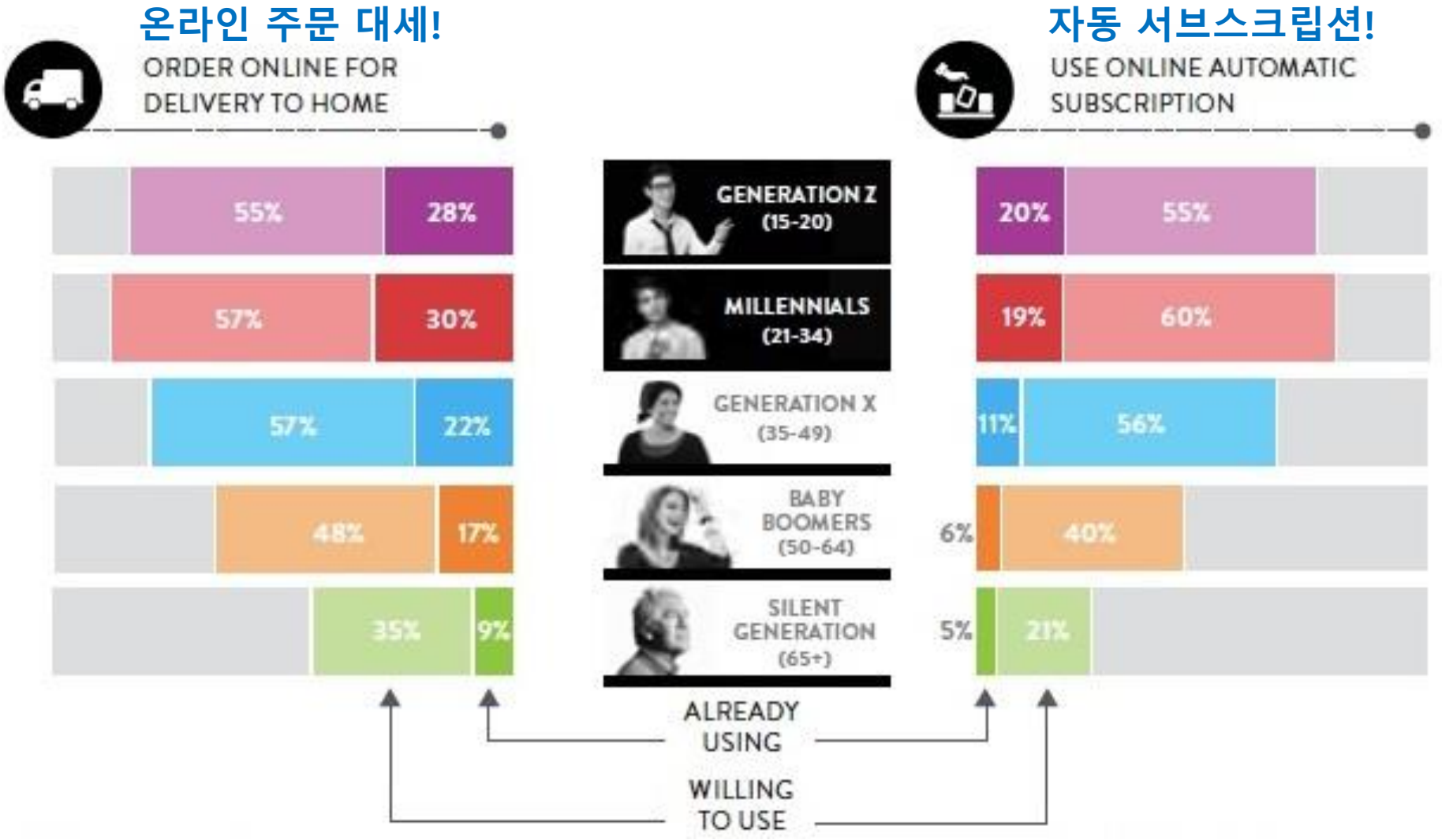
BSBO 오프라인>온라인
BOBO 온라인>온라인



Note: Figures may not sum to 100%, because of rounding.
[1]Question: How do you purchase [cosmetics and skin-care products] most often? (n = 10,000).
Source: McKinsey New Age of the Consumer Generational Survey 2019

BSBS 오프라인>오프라인

1. Current U.S. Market & Trends 미국 시장, 동향



1. Current U.S. Market & Trends 미국 시장, 동향

미래 유통 시스템?

amazon

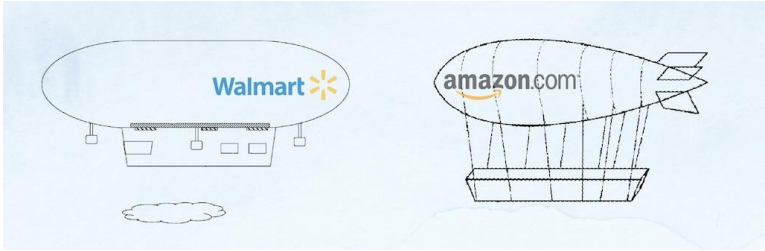
Walmart
Save money. Live better.

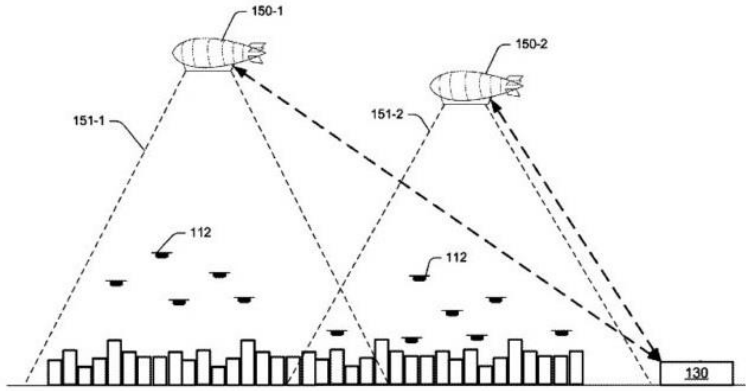
COSTCO WHOLESALE

FedEx

UNITED STATES POSTAL SERVICE

ups





Amazon's newly published patent envisions a fleet of airships that would monitor delivery drones. (Amazon Illustration via USPTO)

2. Cosmetics Regulations 화장품 제도

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Cosmetics & U.S. Law 화장품과 미국법

https://www.fda.gov/media/98748/download

FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated 화장품에 관한 FDA 의 권한: 화장품은 왜 FDA 승인(FDA-Approved)이 아닌 FDA 규제(FDA-Regulated) 대상인가

https://www.fda.gov/media/101073/download

Key Legal Concepts for Cosmetics Industry: Interstate Commerce, Adulterated, and Misbranded 주간 상거래, 부정생산 및 부정표시

https://www.fda.gov/media/94733/download

Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)
화장품인가, 의약품인가? 아니면 둘 다인가? (아니면 비누인가?)

https://www.fda.gov/media/96708/download

3. OTC (Drug) Regulations 일반의약품 제도

3. OTC (Drug) Regulations 일반의약품 제도

OVER THE COUNTER

피부 보호제

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

선스크린

PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE [STAYED INDEFINITELY]

4. Import Procedure 수입 절차

4. Import Procedure 수입 절차

Entry Review 수입통관 리뷰

1. The first step in the importation process is submission of entry information to CBP.
2. After an entry is electronically submitted to Customs and Border Protection (CBP), the data is then sent to FDA for review.
3. When FDA's system receives your entry information, it is electronically screened.
4. If your entry contains all the necessary information and is identified as lower risk, it may receive a release without FDA manual review.

FDA U.S. FOOD & DRUG ADMINISTRATION

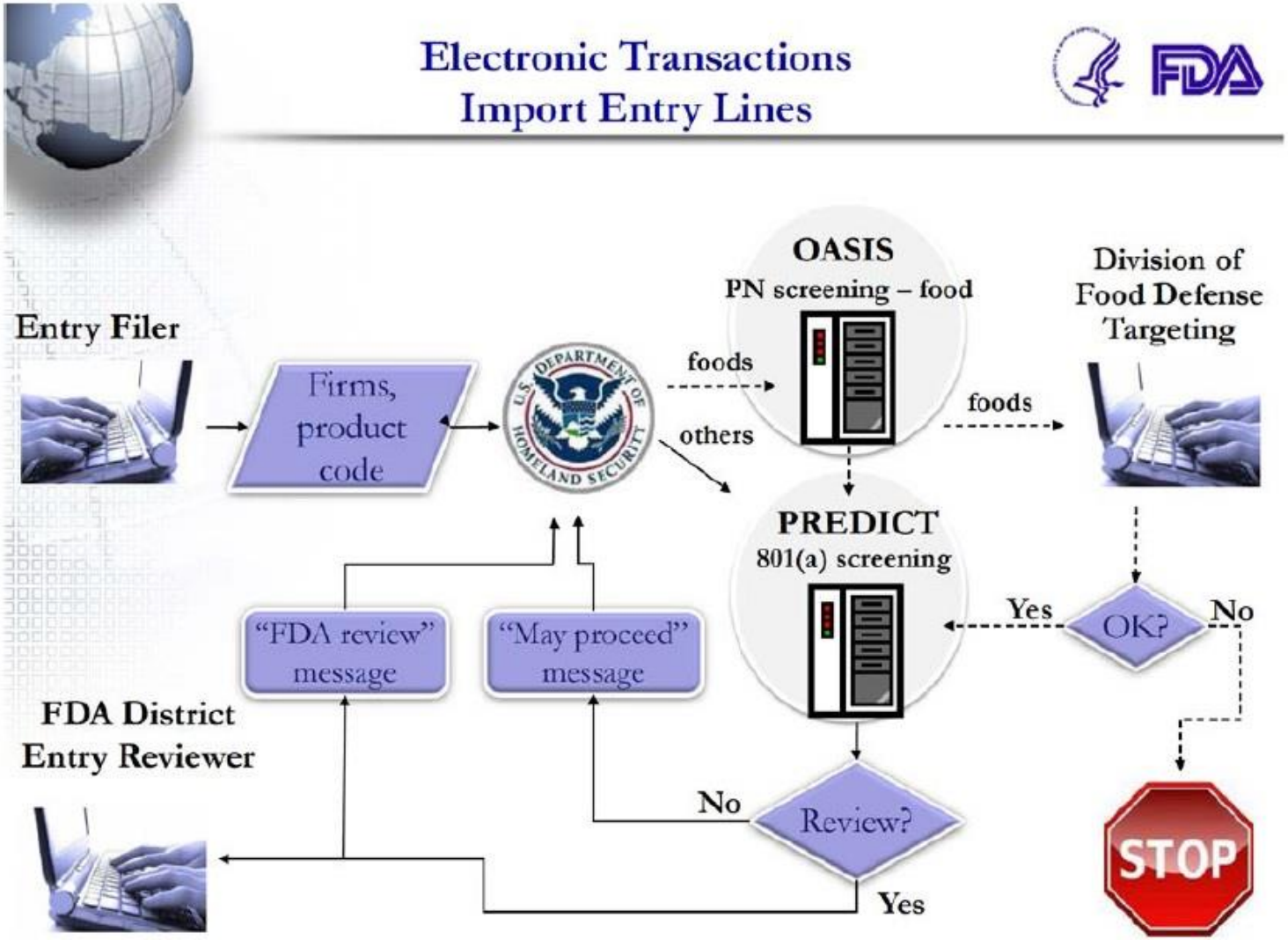
FDA와 CBP(미국 관세국경보호청)은 수입품 모니터링을 위해 긴밀히 협조하는 사이!

U.S. Customs and Border Protection

- **CBP(미 관세국경보호청)에 수입물품신고(전자방식)**
- **FDA 신고 데이터 자동 스크린 리뷰 프로세스**
- **문제가 없을 경우, Release 반출 허가**
- **문제가 있을 경우, Manual Review 수동적 리뷰(검사)**

https://www.fda.gov/industry/entry-submission-process/entry-review

4. Import Procedure 수입 절차



4. Import Procedure 수입 절차

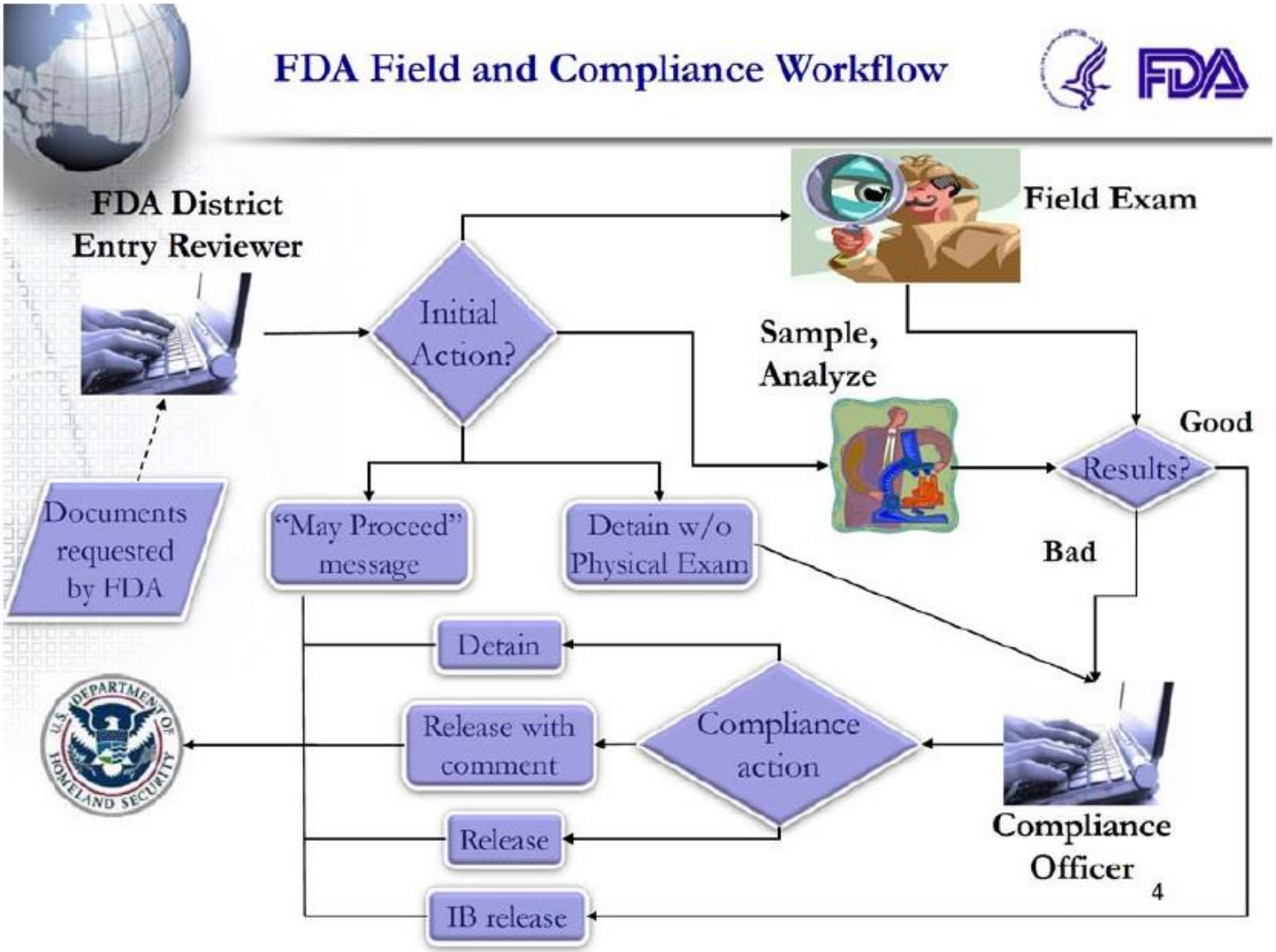
Entry Manual Review 수입통관 수동적 리뷰

1. Any entry that does not receive a release by FDA's system is routed for manual review.
2. Based on the product type and information received, FDA may take one or more of the following actions when reviewing your entry:
   - Release the product
   - Request additional information, either through:
     - Review of entry documents (documents required); and/or
     - Examination/sample collection of the product
   - Request detention of the product

- **Release 반출 허가 다시 검토**
- **추가적 조치 (서류, 검사, 샘플요청)**
- **억류 조치**

https://www.fda.gov/industry/entry-submission-process/entry-review

4. Import Procedure 수입 절차



4. Import Procedure 수입 절차

Common Entry Errors 일반적 수입통관 오류, 문제점

Error	에러, 문제
Submitting the incorrect Affirmation of Compliance (AofC) information	AOC 코드번호
Submitting the incorrect manufacturer information	제조사 정보
Submitting the incorrect product code	제품 코드
Submitting the incorrect quantity	수량 오류
Submitting the incorrect shipper information	수출자 정보
Submitting an inaccurate or incomplete description	제품 정보
Submitting the incorrect device initial importer	수입자 정보
Submitting the incorrect consignee	화주 정보
Submitting the incorrect value	화물 밸류
Submitting the incorrect container dimensions	화물 사이즈
Incorrect intended use code (IUC)	IUC 코드 오류
Incorrect grouping of line items	라인 오류
Submitting the incorrect arrival date	도착 날짜

https://www.fda.gov/industry/entry-process/common-entry-errors

4. Import Procedure 수입 절차

AOC Code Information 준수 확인 코드

Cosmetics		
Code	Affirmation of Compliance	Qualifier?
COS	Cosmetic Registration Number	Y
ERR	Entry Review Requested	N
IFE	Import For Export	N

Drugs		
Code	Affirmation of Compliance	Qualifier?
DA	New Drug Application Number or Abbreviated new Drug Application Number or Therapeutic Biologic Application Number	Y
DLS	Drug Listing Number	Y
ERR	Entry Review Requested	N
IDE	Investigational Device Exemption Number	Y
IND	Investigational New Drug Application Number	Y
LST	Device Listing Number	Y
PLR	Used to identify the shipment as a PLAIR import shipment	N
PM#	Device Premarket Number	Y
REG	Drug Registration Number	Y

원활한 수입통관을 위해 전문 통관(관세)사, 포워딩업체 사용 권장!

5. Import Alert 수입 경보

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What Is an Import Alert? 수입 경보란?

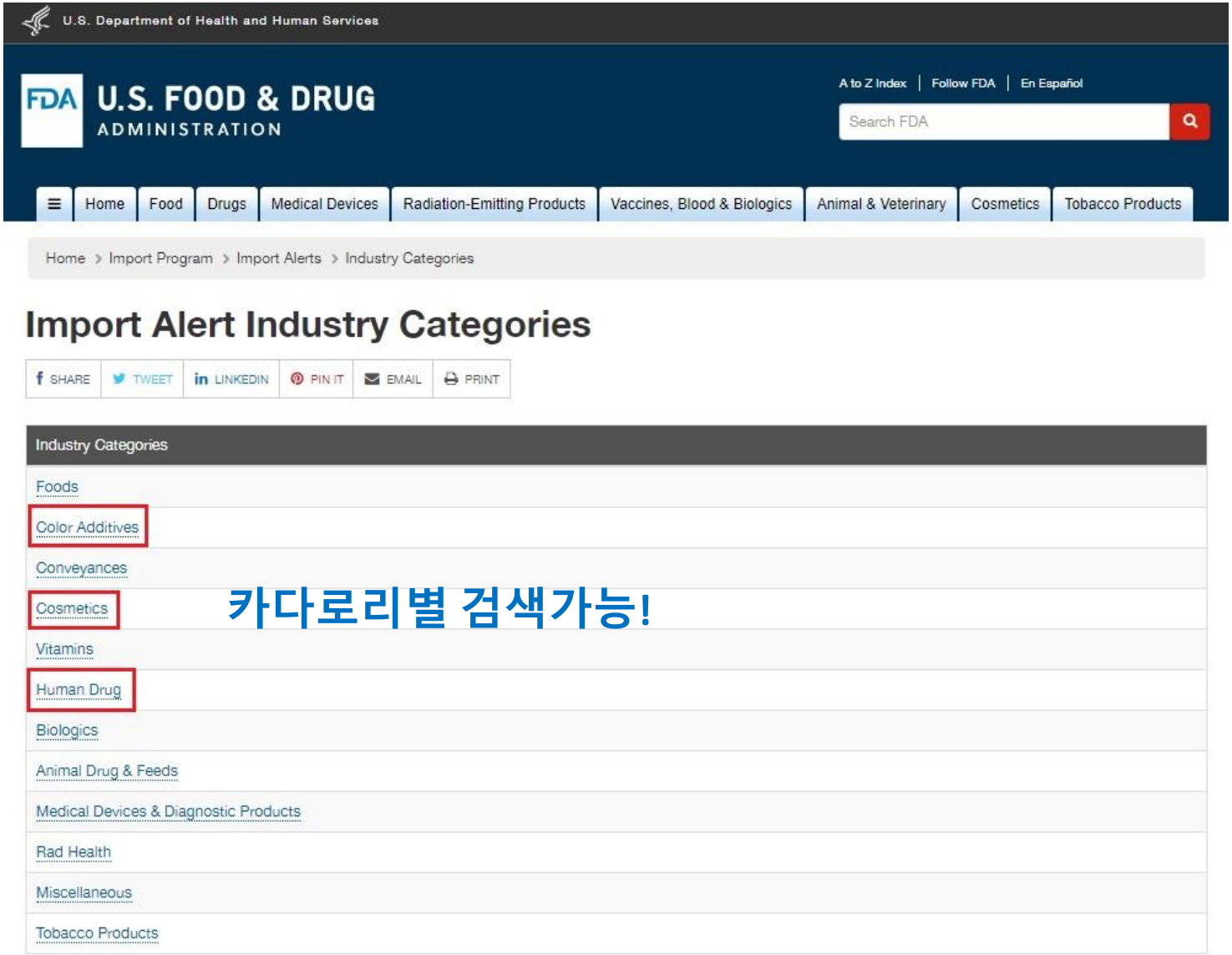
An import alert allows FDA to detain, without physically examining (DWPE), products that either have or potentially could violate the Food, Drug, and Cosmetic Act.

FDA는 식품, 의약품, 화장품법을 위반하거나 잠재적 위반이 판단되는 수입제품에 대해 DWPE(물리적 무검사 억류) 조치

- Violative for a pathogen 바이러스, 세균 검출
- Illegal colors or food additives 불법 색소, 식품첨가물 검출
- Pesticides 살충제
- Insufficient evidence 불충분한 증빙자료
- Unapproved new drug 비승인 의약품, 성분
- Foreign firm violative inspection 해외 제조소 실사 위반
- Foreign firm refused inspection 해외 제조소 실사 거부

https://www.fda.gov/industry/actions-enforcement/import-alerts#dwpe

5. Import Alert 수입 경보



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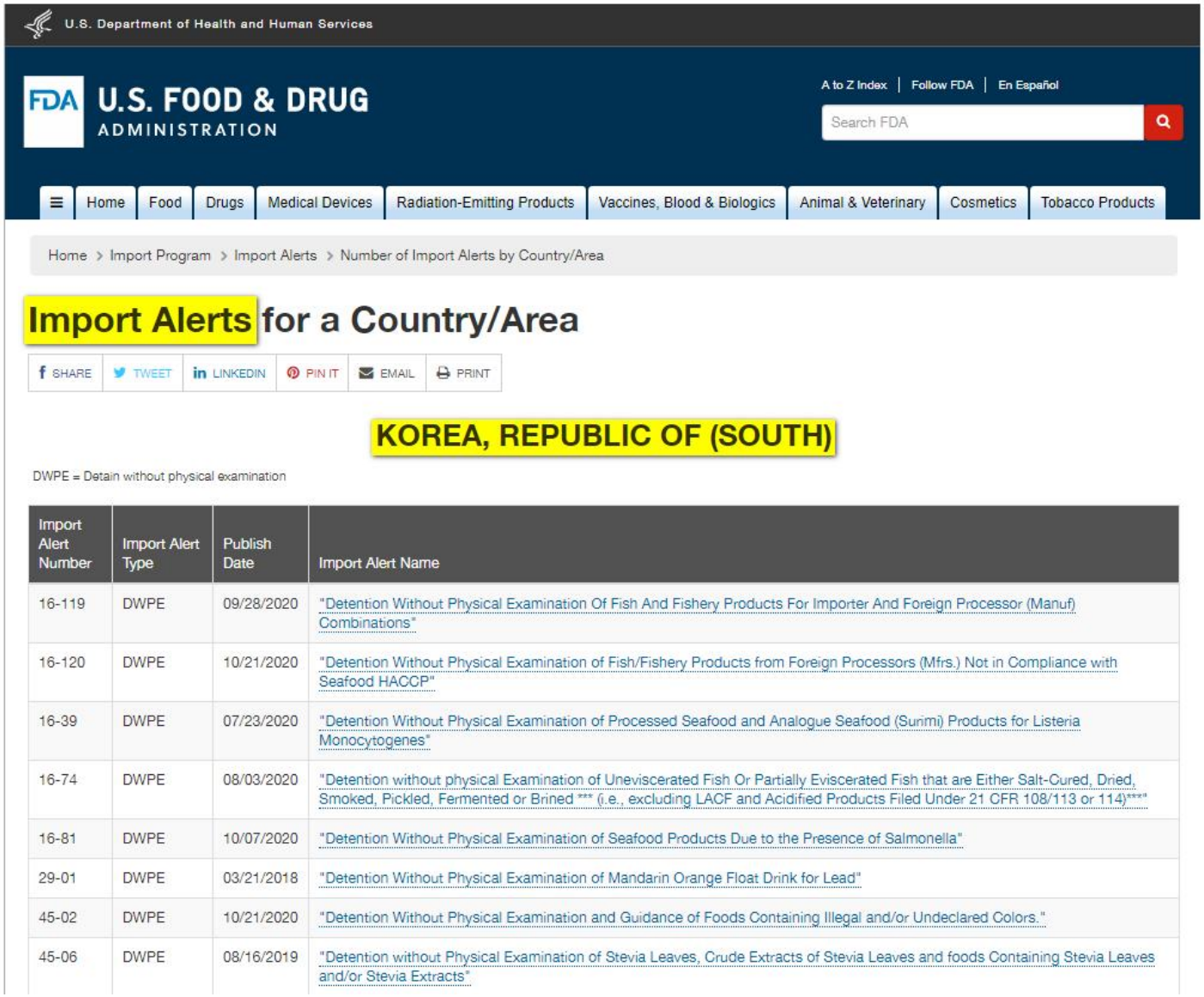

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Home > Import Program > Import Alerts > Number of Import Alerts by Country/Area

Import Alerts for a Country/Area

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

KOREA, REPUBLIC OF (SOUTH)

DWPE = Detain without physical examination

Import Alert Number	Import Alert Type	Publish Date	Import Alert Name
16-119	DWPE	09/28/2020	"Detention Without Physical Examination Of Fish And Fishery Products For Importer And Foreign Processor (Manuf) Combinations"
16-120	DWPE	10/21/2020	"Detention Without Physical Examination of Fish/Fishery Products from Foreign Processors (Mfrs.) Not in Compliance with Seafood HACCP"
16-39	DWPE	07/23/2020	"Detention Without Physical Examination of Processed Seafood and Analogue Seafood (Surimi) Products for Listeria Monocytogenes"
16-74	DWPE	08/03/2020	"Detention without physical Examination of Uneviscerated Fish Or Partially Eviscerated Fish that are Either Salt-Cured, Dried, Smoked, Pickled, Fermented or Brined *** (i.e., excluding LACF and Acidified Products Filed Under 21 CFR 108/113 or 114)***"
16-81	DWPE	10/07/2020	"Detention Without Physical Examination of Seafood Products Due to the Presence of Salmonella"
29-01	DWPE	03/21/2018	"Detention Without Physical Examination of Mandarin Orange Float Drink for Lead"
45-02	DWPE	10/21/2020	"Detention Without Physical Examination and Guidance of Foods Containing Illegal and/or Undeclared Colors."
45-06	DWPE	08/16/2019	"Detention without Physical Examination of Stevia Leaves, Crude Extracts of Stevia Leaves and foods Containing Stevia Leaves and/or Stevia Extracts"

5. Import Alert 수입 경보

52-08	DWPE with Surveillance	04/07/2020	"Detention Without Physical Examination of Ceramicware Due to Excessive Lead and/or Cadmium"
53-06	DWPE	10/05/2020	"Detention Without Physical Examination Of Cosmetics That are Adulterated and/or Misbranded Due to Color Additive Violations"
53-17	DWPE	05/26/2020	"Detention Without Physical Examination of Cosmetics Due To Microbiological Contamination"
54-07	DWPE	04/23/2019	"Germanium Products"
54-13	DWPE	01/09/2020	"Detention Without Physical Examination of Dietary Supplements And Bulk Dietary Ingredients Containing Ephedrine Alkaloids From All Countries"
54-16	DWPE	10/26/2020	"DETENTION WITHOUT PHYSICAL EXAMINATION OF PRODUCTS THAT ARE MARKETED AS FOODS, INCLUDING PRODUCTS MARKETED AS DIETARY SUPPLEMENTS, THAT CONTAIN AN ACTIVE PHARMACEUTICAL INGREDIENT"
55-05	DWPE	06/19/2019	DETENTION WITHOUT PHYSICAL EXAMINATION OF FINISHED DOSAGE DRUG PRODUCTS, ACTIVE PHARMACEUTICAL INGREDIENTS AND INACTIVE INGREDIENTS FOR POTENTIALLY HAZARDOUS MICROBIOLOGICAL CONTAMINATION
66-10	DWPE	03/18/2011	Chinese Herbal Medicines
66-40	DWPE	10/22/2020	"Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug GMPs"
66-41	DWPE	10/27/2020	Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S.
66-57	DWPE	03/16/2020	"Detention Without Physical Examination Of Foreign manufactured Unapproved Prescription Drugs Promoted to Individuals in the U.S."
66-66	DWPE	09/08/2020	"APIs That Appear To Be Misbranded Under 502(f)(1) Because They Do Not Meet The Requirements For The Labeling Exemptions In 21 CFR 201.122"
79-01	DWPE with Surveillance	06/04/2019	"Detention Without Physical Examination Plastic Bandages And Cotton Pads Due To Microbiological Contamination"
80-04	DWPE with Surveillance	09/16/2020	"Surveillance and Detention Without Physical Examination of Surgeon's and Patient Examination Gloves"
80-06	DWPE	08/25/2020	"Detention Without Physical Examination of Medical Devices with False or Misleading Labeling"

중금속(납,카드뮴), 색소, 미생물 오염, GMP기준 미달, 허위 라벨 문제 등

5. Import Alert 수입 경보

85-02	DWPE	05/27/2020	"Detention Without Physical Examination of Condoms"
86-11	DWPE	11/30/2016	DETENTION WITHOUT PHYSICAL EXAMINATION OF CONTACT LENSES DUE TO MICROBIOLOGICAL CONTAMINATION
89-01	DWPE with Surveillance	09/15/2015	"Electrical Muscle Stimulators and Iontophoresis Devices"
89-04	DWPE	09/29/2020	"Detention Without Physical Examination of Devices from Firms that Have not met Device Quality System Requirements"
89-08	DWPE	10/22/2020	"Detention Without Physical Examination of Devices without Approved PMA's or IDE's and Other Devices Not Substantially Equivalent or Without a 510(K)"
99-05	DWPE	10/07/2020	"Detention Without Physical Examination Of Raw Agricultural Products for Pesticides"
99-08	DWPE	10/22/2020	"Detention without Physical Examination of Processed Human and Animal Foods for Pesticides"
99-19	DWPE	10/22/2020	"Detention Without Physical Examination Of Food Products Due To The Presence Of Salmonella"
99-21	DWPE with Surveillance	10/23/2020	"Detention Without Physical Examination and Surveillance Of Food Products Containing Sulfites"
99-22	DWPE	08/06/2020	Detention Without Physical Examination Of Foods Containing Undeclared Major Food Allergens Or Foods That Fail To Properly Label Major Food Allergens
99-23	DWPE	09/21/2020	Detention Without Physical Examination of Produce Due to Contamination With Human Pathogens
99-31	DWPE	02/05/2020	"Detention Without Physical Examination of Food Products Due to the Presence of Melamine and/or Melamine Analogs"
99-32	DWPE	10/14/2020	"DETENTION WITHOUT PHYSICAL EXAMINATION OF PRODUCTS FROM FIRMS REFUSING FDA FOREIGN ESTABLISHMENT INSPECTION"
99-34	DWPE	12/13/2019	DETENTION WITHOUT PHYSICAL EXAMINATION OF DRUGS OR MEDICAL DEVICES FROM FIRMS WITHOUT A VALID DRUG OR MEDICAL DEVICE REGISTRATION
99-35	DWPE	10/09/2020	DETENTION WITHOUT PHYSICAL EXAMINATION OF FRESH PRODUCE THAT APPEARS TO HAVE BEEN PREPARED, PACKED OR HELD UNDER INSANITARY CONDITIONS
99-36	DWPE	04/01/2019	"DETENTION WITHOUT PHYSICAL EXAMINATION OF LOW-ACID CANNED FOODS AND ACIDIFIED FOODS FROM COMMERCIAL PROCESSORS FOR FAILURE TO PROVIDE PROCESS INFORMATION"
99-37	DWPE	10/23/2020	"DETENTION WITHOUT PHYSICAL EXAMINATION OF LOW-ACID CANNED FOODS AND ACIDIFIED FOODS WITHOUT FILED SCHEDULED PROCESSES"
99-38	DWPE	10/23/2020	"DETENTION WITHOUT PHYSICAL EXAMINATION OF LOW-ACID CANNED FOODS OR ACIDIFIED FOODS DUE TO INADEQUATE PROCESS CONTROL"
99-39	DWPE	10/26/2020	Detention Without Physical Examination of Imported Food Products appear To Be Misbranded

미생물 오염

제조소 실사 비협조,거부

5. Import Alert **수입 경보**

What do I do if my product is detained without physical examination (DWPE)? 억류 조치된 수입제품 어떻게 해야하나?

If your product is detained without physical examination, you have the right to provide evidence to the FDA in an attempt to overcome the appearance of the violation. If you do not provide evidence to the FDA, or if the information you provide is not sufficient to overcome the appearance of the violation, your product is subject to refusal into the United States.

- **위반 사항에 대한 즉각 대응:** 증거, 증빙자료, 어필레터 등 제출
- **무대응, 불충분 한 제출자료:** 수입 경보 영구적 리스트
- **리스트 제거/삭제 프로세스:** 청원서, 신청서, 증빙자료 등 제출
  시간적(30~360일+), 금전적(검사비용, 운송, 보관, 컨설팅, 법률자문 비용 등) 막대한 손실
- **수입 경보 위반업체(제조소) 리스트 확인:** FDA 웹사이트 공개

https://www.fda.gov/industry/actions-enforcement/import-alerts#dwpe

6. Import Refusal 수입 거부

6. Import Refusal 수입 거부

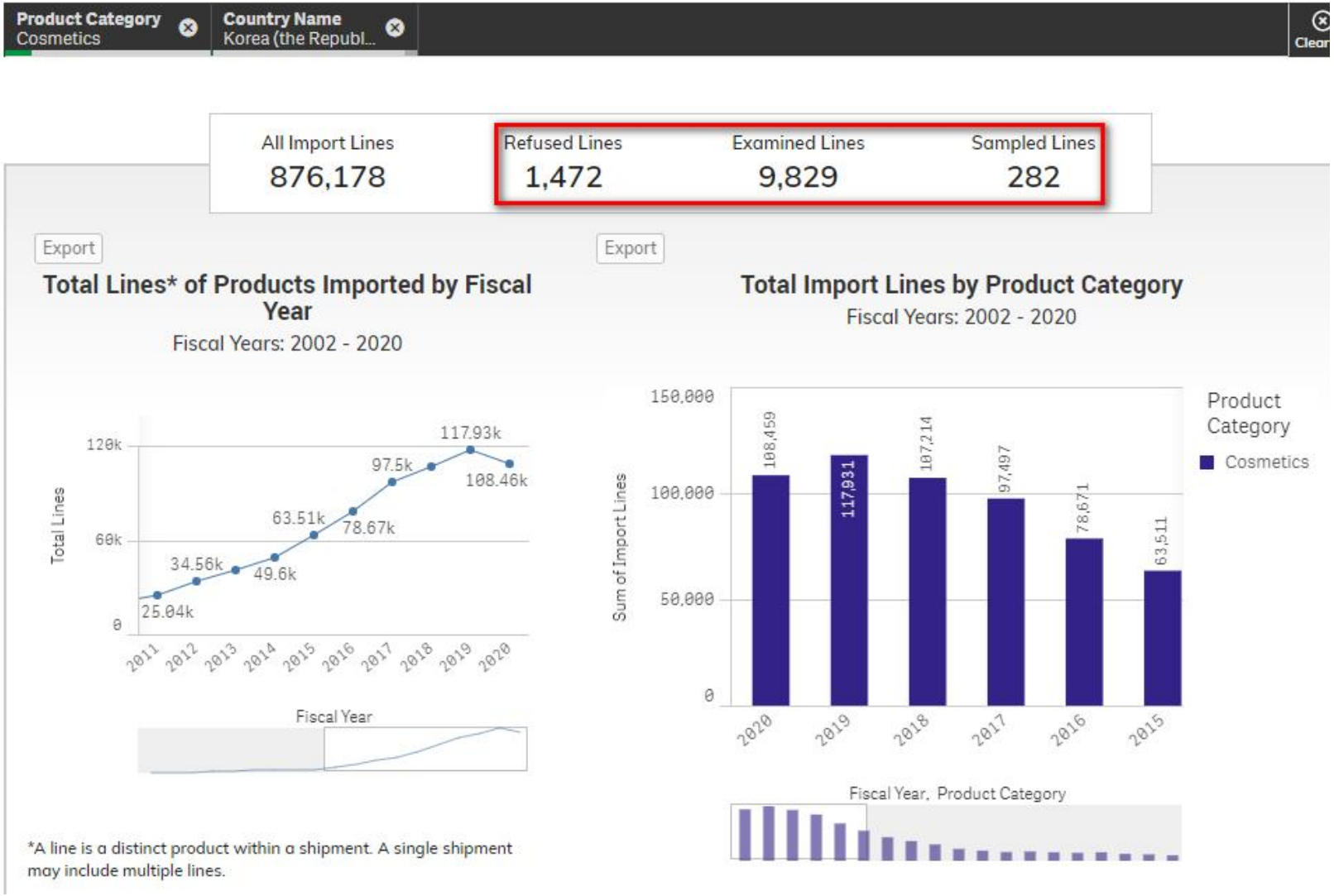
What is an import refusal? 수입 거부란?

A refusal is FDA's final decision that a detained shipment is in violation of FDA laws and regulations. A refused shipment must either be destroyed or exported under the supervision of Customs and Border Protection (CBP) and FDA within 90 days of the date of the Notice of FDA Action (Refusal Notice).

- **FDA의 억류된 수입제품에 대한 최종적 결론, 통보**
- **최종 결론에 대한 항소 및 어필 레터 제출 가능**
- **수입 거부 조치된 선적은 FDA 최종 통보 날짜부터 90일안**
  - **폐기처분 처리 (소량, 샘플)**
  - **리턴선적 처리 (대량, 고가)**
- **90일안에 처리못할 경우, 고액의 과태료 및 손해금 청구**

https://www.fda.gov/industry/actions-enforcement/import-refusals

6. Import Refusal 수입 거부



6. Import Refusal 수입 거부

2014-2020 Import Refusal by Product Type South Korea

1. **SKINCARE PRODUCTS** (FACE/BODY/HAND: CLEANSER, MOISTURIZER, LOTION, CREAM)
2. **SUNSCREEN PRODUCTS (SPF)**
3. **EYE MAKEUP** (EYEBROW PENCIL, EYELINER, EYE SHADOW, EYE LOTION, MASCARA)
4. **FACE/LIP MAKEUP** (BASE, FOUNDATION, BLUSHERS, LIPSTICK, LIPTINT)
5. **HERBAL** (GINSENG, BOTANICALS)
6. **HAIR PRODUCTS** (SHAMPOO, CONDITIONERS, DYE, TINT)
7. **BATH SOAP** (FACE, BODY)

* COVID-19 (ALCOHOL HAND SANITIZERS, WIPES, TEST KITS) 3Q+
* CONTACT LENS (DAILY, COLOR, CIRCLE) M/D

6. Import Refusal 수입 거부

Imports Summary Details **

Record Count: 19

2017년 & 2019년 거부, 검사 High!

Fiscal Year	Product Category	Country/Area	Total Lines	Refused Lines	Examined Lines	Sampled Lines
2020	Cosmetics	Korea (the Republic of)	108459	85	584	48
2019	Cosmetics	Korea (the Republic of)	117931	96	476	26
2018	Cosmetics	Korea (the Republic of)	107214	133	717	8
2017	Cosmetics	Korea (the Republic of)	97497	126	1398	24
2016	Cosmetics	Korea (the Republic of)	78671	152	996	54
2015	Cosmetics	Korea (the Republic of)	63511	90	1146	10
2014	Cosmetics	Korea (the Republic of)	49596	68	401	36
2013	Cosmetics	Korea (the Republic of)	41603	52	464	8
2012	Cosmetics	Korea (the Republic of)	34565	101	515	9
2011	Cosmetics	Korea (the Republic of)	25044	161	644	19
2010	Cosmetics	Korea (the Republic of)	21329	121	545	6
2009	Cosmetics	Korea (the Republic of)	18563	101	529	3
2008	Cosmetics	Korea (the Republic of)	19581	68	365	9
2007	Cosmetics	Korea (the Republic of)	18170	15	80	2

7. FDA Foreign Inspection 해외 제조소 감사

7. FDA Foreign Inspection 해외 제조소 감사

What is an inspection? 제조소 감사/실사란?

The Food and Drug Administration (FDA) conducts inspections and assessments of regulated facilities to determine a firm's compliance with applicable laws and regulations, such as the Food, Drug, and Cosmetic Act. This typically involves an investigator visiting a firm's location.

- **화장품 부정 생산,불량(Adulterated), 부정표시(Misbranded)**
- **보통 2년 또는 4년에 한번**
- **화장품 제조소 보다는 OTC 제조소 우선적**

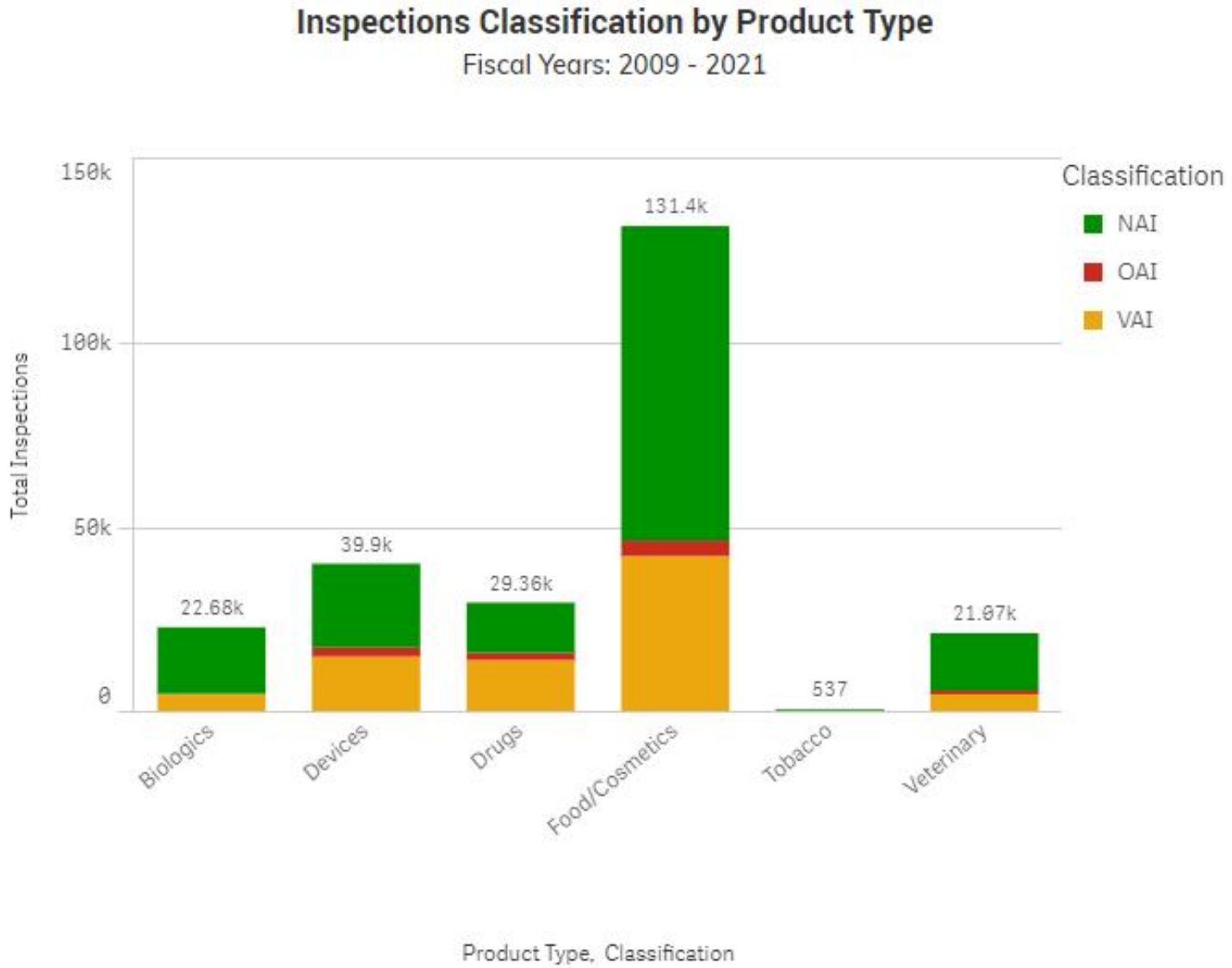
No Action Indicated (NAI) which means no objectionable conditions or practices were found during the inspection (or the objectionable conditions found do not justify further regulatory action),

Voluntary Action Indicated (VAI) which means objectionable conditions or practices were found but the agency is not prepared to take or recommend any administrative or regulatory action, or

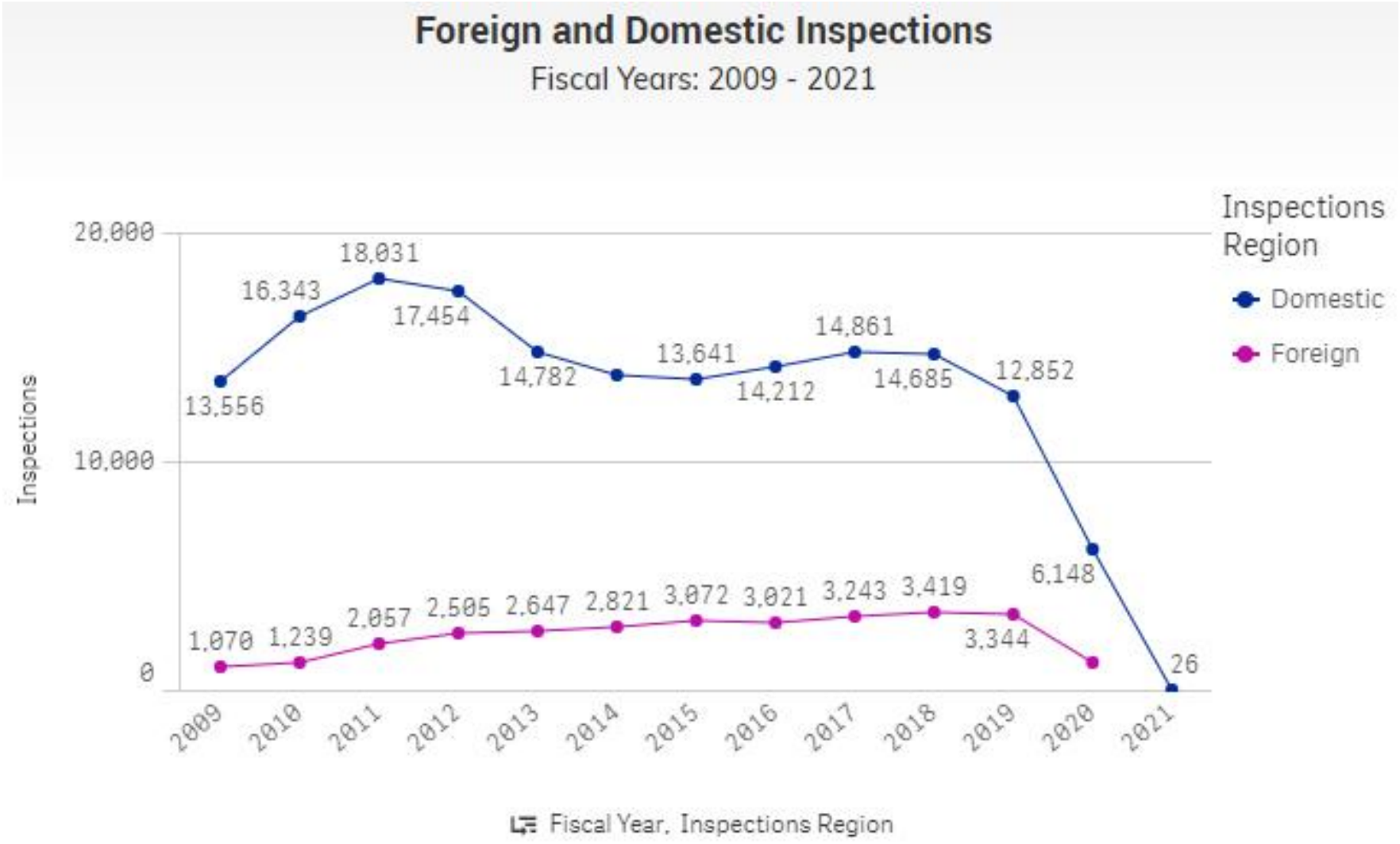
Official Action Indicated (OAI) which means regulatory and/or administrative actions will be recommended.

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspections-database-frequently-asked-questions

7. FDA Foreign Inspection 해외 제조소 감사



7. FDA Foreign Inspection 해외 제조소 감사



8. FAQ 자주 묻는 질의 Cosmetics

8. FAQ 자주 묻는 질의 Cosmetics

- Does FDA approve cosmetics before they go on the market?
  시판전 FDA 승인이 필요한가요?
- Does FDA pre-approve cosmetic product labeling?
  시판전 FDA에서 라벨링 사전 승인을 해주나요?
- Are cosmetic companies required to register with FDA?
  화장품 회사들은 FDA 업체등록이 필수조건인가요?
- Are all "personal care products" regulated as cosmetics?
  모든 퍼스너 케어 제품은 화장품으로 규제를 받나요?
- Do I need to label my products with expiration dates?
  제품 라벨에 유효기간 표기해야 하나요?
- How can I tell if my product is a cosmetic, a drug, or both?
  우리 제품이 화장품인지? 의약품인지? 아니면 둘다인지 어떻게 구분할수있나요?
- Where can I find more FDA resources for the cosmetics industry?
  화장품 업계를 위한 추가 정보는 어디서 찾을수 있나요?

8. FAQ 자주 묻는 질의 Cosmetics

- Does FDA approve cosmetics before they go on the market?
  시판전 FDA 승인이 필요한가요?

Cosmetic products and ingredients are not subject to FDA premarket approval authority, with the exception of color additives (other than those intended for use as coal-tar hair dyes). In addition, there are some cosmetic ingredients that are prohibited and restricted by regulation. Companies and individuals who market cosmetics have a legal responsibility for the safety of their products and ingredients.

FDA's authority over cosmetics is post-market. FDA may take regulatory action if it has information to support that a cosmetic is adulterated or misbranded. The agency can pursue action through the Department of Justice in the federal court system to remove adulterated and misbranded cosmetics from the market. To prevent further shipment of an adulterated or misbranded product, the agency may request a federal district court to issue a restraining order against the manufacturer or distributor of the violative cosmetic. Violative cosmetics may be subject to seizure. FDA also may initiate criminal action against a person violating the law. For more information, see "FDA Authority Over Cosmetics."

8. FAQ 자주 묻는 질의 Cosmetics

- Does FDA pre-approve cosmetic product labeling?
  시판전 FDA에서 라벨링 사전 승인을 해주나요?

No. FDA does not have the authority under the law for pre-market approval of cosmetic product labeling. It is the manufacturer's and/or distributor's responsibility to ensure that products are labeled properly. Failure to comply with labeling requirements may result in a misbranded product.

For an overview of cosmetic labeling requirements, see "Labeling Regulations".

For a "how-to" guideto cosmetic labeling, including answers to common questions, with examples, see the "Cosmetic Labeling Guide".

For links to the cosmetic labeling regulations, see "Labeling Regulations: CFR Title 21, Part 701".

For information on cosmetic vs. drug claims, "organic," aromatherapy, and more, see "Labeling Claims".

For information on identifying cosmetic ingredients on cosmetic labels, see "Ingredient Names".

8. FAQ 자주 묻는 질의 Cosmetics

- Are cosmetic companies required to register with FDA?
  화장품 회사들은 FDA 업체등록이 필수조건인가요?

No. Cosmetic registration in the United States is voluntary, not mandatory. Also, no registration number is required to import cosmetics into this country.

However, FDA encourages cosmetic firms to register their establishments and file Cosmetic Product Ingredient Statements through our Voluntary Cosmetic Registration Program (VCRP). The VCRP helps FDA in its mission to protect consumers, while also helping cosmetic manufacturers and distributors make informed decisions. Participating in the VCRP puts manufacturers in the pipeline for important information about cosmetic ingredients. The VCRP also supports the safety evaluation of cosmetic ingredients. The greater the participation by the cosmetic industry, the better this program works.

To learn more about this program and to participate, either online or by mail, please see Voluntary Cosmetic Registration Program (VCRP).

8. FAQ 자주 묻는 질의 Cosmetics

- Are all "personal care products" regulated as cosmetics?
  모든 퍼스너 케어 제품은 화장품으로 규제를 받나요?

Under the law, some of the products commonly referred to as "personal care products" are cosmetics. These include, for example, skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes, and deodorants. Some, however, are regulated as drugs. Among these are skin protectants (such as lip balms and diaper ointments), mouthwashes marketed with therapeutic claims, antiperspirants, and treatments for dandruff or acne.

Some "personal care products" meet the definitions of both cosmetics and drugs. This may happen when a product has two intended uses. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair. An antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug, because it is intended to cleanse the hair and treat dandruff. Among other cosmetic/drug combinations are toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims. Such products must comply with the requirements for both cosmetics and drugs.

In addition, some "personal care products" may belong to other regulatory categories, including medical devices (such as certain hair removal and microdermabrasion devices), dietary supplements (such as vitamin or mineral tablets or capsules), or other consumer products (such as manicure sets).

8. FAQ 자주 묻는 질의 Cosmetics

- Do I need to label my products with expiration dates?
  제품 라벨에 유효기간 표기해야 하나요?

There are no regulations or requirements under current United States law that require cosmetic manufacturers to print expiration dates on the labels of cosmetic products. Manufacturers have the responsibility to determine shelf life for products, as part of their responsibility to substantiate product safety. FDA believes that failure to do so may cause a product to be adulterated or misbranded.

Shelf Life and Expiration Dating of Cosmetics

Does FDA have rules for cosmetic shelf life and expiration dates on cosmetic labels?

There are no U.S. laws or regulations that require cosmetics to have specific shelf lives or have expiration dates on their labels. However, manufacturers are responsible for making sure their products are safe. FDA considers determining a product's shelf life to be part of the manufacturer's responsibility.

8. FAQ 자주 묻는 질의 Cosmetics

- How can I tell if my product is a cosmetic, a drug, or both?
  우리 제품이 화장품인지? 의약품인지? 아니면 둘다인지 어떻게 구분할수있나요?

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines cosmetics, in part, by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" (FD&C Act, sec. 201(i)). The FD&C Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" (FD&C Act, sec. 201(g)(1)). Some skin care products are regulated as cosmetics. Others are regulated as drugs, or as combination drug-cosmetic products. For example, acne treatments, dandruff treatments, and skin protectants are regulated as drugs. A cleanser that is also an acne treatment, or a shampoo that is also a dandruff treatment is regulated as a combination drug-cosmetic. The requirements for cosmetics and drugs are different. Products that are both drugs and cosmetics must meet the requirements for both categories.

8. FAQ 자주 묻는 질의 (Cosmetics)

- Where can I find more FDA resources for the cosmetics industry?
  화장품 업계를 위한 추가 정보는 어디서 찾을수 있나요?

Resources for Industry on Cosmetics

FDA information and links to resources commonly requested by the cosmetics industry
https://www.fda.gov/cosmetics/resources-you-cosmetics/resources-industry-cosmetics#Laws

FDA Basics for Industry**기본 FDA 정보**
https://www.fda.gov/industry

Cosmetics Labeling Regulations
https://www.fda.gov/cosmetics/cosmetics-labeling/cosmetics-labeling-regulations

Cosmetics Labeling Claims **화장품 라벨링 표기, 소구**
https://www.fda.gov/cosmetics/cosmetics-labeling/cosmetics-labeling-claims

Wrinkle Treatments and Other Anti-aging Products **주름개선, 노화방지**
https://www.fda.gov/cosmetics/cosmetic-products/wrinkle-treatments-and-other-anti-aging-products

Color Additives **색상 첨가제**
https://www.fda.gov/industry/color-additives

Color Additives Permitted for Use in Cosmetics **화장품 허용 색상 첨가제**
https://www.fda.gov/cosmetics/cosmetic-ingredient-names/color-additives-permitted-use-cosmetics

Color Additive Status List **색상 첨가제 현황 리스트**
https://www.fda.gov/industry/color-additive-inventories/color-additive-status-list

Prohibited & Restricted Ingredients in Cosmetics **사용금지 성분**
https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics

Q&A 미국 수출 관련 사전 질의사항

U.S. FOOD & DRUG
ADMINISTRATION

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Launch in Early November 2020

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