

미국 자외선차단제 관련 규정

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자외선차단제 : 한국에서는 화장품, 미국에서는 OTC Drug

한국에서 자외선차단제의 정의

피부를 곱게 태워주거나 자외선으로부터 피부를 보호하는 데에 도움을 주는 제품

미국에서 UV-필터와 자외선차단제는 법적으로 의약품으로 정의되며 FDA의 일반의약품 (OTC, Over the Counter) 자외선차단제 모노그래프 (M020) 하에 규제됩니다.

"질병의 진단, 치유, 완화, 치료, 또는 예방의 목적으로 사용되는 제품..."

목적 및 용도:

햇볕으로 인한 화상을 예방하거나 일광으로 인한 피부 암의 위험성을 감소시키고 피부 조기 노화 위험성을 감소시키는데 도움을 줌

In the US, UV-filters and sunscreen products are **legally defined to be drugs** and are **regulated by FDA under the Over the Counter (OTC) Sunscreen Drug Products Monograph (M020)**

*"articles intended for use in the diagnosis, cure, mitigation, treatment, or **prevention** of disease..."*

Intended use and indications:

To help **prevent sunburn** or to **decrease the risks of skin cancer** and **early skin aging** caused by the sun

OTC Drug 란?

OTC Drug = 비처방 의약품 = 일반 의약품

- 의사 등의 지도 없이도 안전하게 사용할 수 있는 의약품

▷ 처방전 없이 시장에서 소비자가 구매 가능

OTC monograph



- Generally Recognized as Safe (GRAS)
- 제품 분류별 활성성분, 용량, 용법, 사용 대상, 라벨링, 경고문구 등에 대한 세부 요건 수록 (일종의 레서피 북)
- 자외선차단제, 비듬방지, 발한억제제, 여드름용 제품, 피부 보호제 등

Sunscreen Drug Products for Over-the-Counter Human Use

Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis for Over-the-Counter Human Use

Antiperspirant Drug Products for Over-the-Counter Human Use

Topical Acne Drug Products for Over-the-Counter Human Use

Skin Protectant Drug Products for Over-the-Counter Human Use

<https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/historical-status-otc-rulemakings>

Historical Status of OTC Rulemakings

The Over-the-Counter (OTC) drug category web site contains *Federal Register* notices organized by therapeutic category subtopics. Each web page also links to therapeutic category pages organized chronologically.

This rulemaking history site is intended as a research aid and is not an official FDA record. We have tried to make these histories accurate and complete. Should you find an error, however, please let us know so that we can correct it.

[A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#)

[A](#)

[Acne](#)

[Administrative Procedures](#)

[Alcohol](#)

[Allergy](#)

[Analgesic, External](#)

[Analgesic, Internal](#)

[Anorectal](#)

[Antacid](#)

[Anthelmintic](#)

[Antibiotic, First Aid](#)

[L](#)

[Labeling](#)

[Laxative](#)

[Leg Muscle Cramps](#)

[M](#)

[Male Genital Desensitizers](#)

[Menstrual](#)

[N](#)

[Nailbiting](#)

[Nasal Decongestant](#)

[Nighttime Sleep Aid](#)

OTC Drug 제품 검색

OTC Drug 제품 예시

Dailymed 웹사이트 <https://dailymed.nlm.nih.gov/dailymed/>

자외선차단제 Sunscreen Drug Products for Over-the-Counter Human Use

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8e294a61-97e2-4df8-8a59-7cec12c6f016>

<https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=96d72471-de95-4668-8903-aed6187633a9&version=1>

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=59c7060a-8cce-4ffa-addf-73d3ed6eca10>

비듬방지 Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis for Over-the-Counter Human Use

<https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=094f0ce7-51f3-4853-ba3b-26f27f1b604a>

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7a4c6b8a-24db-4a76-b9c0-aeec21a862e9>

발한억제제 Antiperspirant Drug Products for Over-the-Counter Human Use

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=dca19c20-0225-7304-e053-2995a90a1bb2>

여드름용 제품 Topical Acne Drug Products for Over-the-Counter Human Use

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0682cb55-6ae3-437f-e063-6294a90ac510>

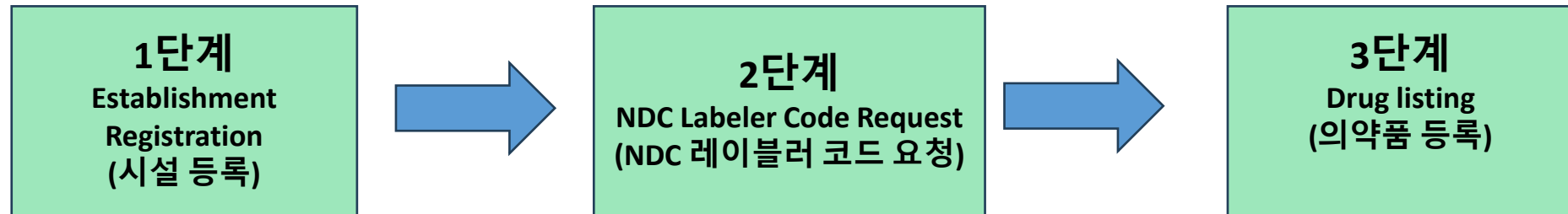
<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e105ed47-d161-4563-a05f-f2e245659aee>

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b03bdef4-a099-4543-8673-85466bd64961>

피부 보호제 Skin Protectant Drug Products for Over-the-Counter Human Use

<https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=32eaaaab-41bd-4efe-a71d-92e3a702c1e5&version=3>

OTC Drug 시설 등록 => 레이블러 코드 요청 => 제품 등록



- ◆ 상업적 유통을 위한 의약품의 제조, 재포장, 재라벨링, 또는 회수에 관여되는 시설은 FDA에 그 해당 시설을 등록해야 함

- ◆ 다음의 정보를 제출

- Registrant Details
- Registrant Contact Details
- Registrant Contact Address
- Establishment Details
- Establishment Address
- Establishment Contact Details
- Establishment Contact Address
- U.S. Agent
- Importers
- Business Operation
- Business Operation Qualifier

- ◆ **Labeler code**는 **National Drug Code(NDC : 국가 의약품 코드)**를 생성하기 위해 필요

- ◆ 다음의 정보를 제출

- Name and DUNS number of the company
- Contact information of someone responsible for receiving FDA communications related to product listings with NDCs under that labeler code

- ◆ 다음의 정보를 제출

- **National Drug Code(NDC) number**
- Product Name
- Dosage Form
- Route of Administration
- Ingredients
- Packaging Information
- Manufacturers' Information
- Labeling

1단계 : OTC Drug 시설 등록시 필요한 정보

- 상업적 유통을 위한 의약품의 제조, 재포장, 재라벨링, 또는 회수에 관여되는 시설은 FDA에 그 해당 시설을 등록해야 함
- 외국 시설(미국 외 시설)의 경우 : OTC Drug 제품이 미국으로 수입될 때, 미리 FDA에 등록이 되어 있어야 함
- 등록 갱신(업데이트)은 매해 10월 1일 ~ 12월 31일 사이에 해야 함
- 아래 링크의 FDA의 강의 33분~43분에 Establishment Registration 시연 영상을 볼 수 있음

<https://www.youtube.com/watch?v=iCnEgx-ZOcE>

◆ 다음의 정보를 온라인으로 제출 CDER Direct https://direct.fda.gov/apex/f?p=100:LOGIN_DESKTOP

- Registrant Details (**Name**, **DUNS**)
- Registrant Contact Details (**Name**, **Email**, **Phone**, Phone Extension)
- Registrant Contact Address (**Country**, **Street Address**, **City**, **State**, Postal Code)
- Establishment Details (**Name**, **DUNS**, FEI)
- Establishment Address (**Country**, **Street Address**, **City**, State, Postal Code)
- Establishment Contact Details (**Name**, **Email**, **Phone**, Phone Extension)
- Establishment Contact Address (**Country**, **Street Address**, **City**, State, Postal Code)
- U.S. Agent (**Name**, **DUNS**, **Email**, **Phone**, Phone Extension)
- Importers (**Name**, **DUNS**, **Email Phone**, Extension)
- Business Operation (e.g., manufacturing, repackaging, relabeling, testing) <https://www.fda.gov/industry/structured-product-labeling-resources/business-operation>
- Business Operation Qualifier <https://www.fda.gov/industry/structured-product-labeling-resources/business-operation-qualifier>



DUNS
번호를
미리
받아놓아야
해요 !


1단계 : OTC Drug 시설 등록시 필요한 정보

FEI가 뭐예요?

FEI Search Portal

<https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login>

FEI (FDA Establishment Identification number)는 FDA가 규제 대상 시설에 발급하는 고유 식별자입니다.



[Home](#) / [FEI Search Portal](#)

FEI Search Portal

[Share](#) [Tweet](#) [LinkedIn](#) [Email](#) [Print](#)

The FEI Portal allows a user to look up a FDA Establishment Identifier (FEI) based on a firm name and address or validate an address of an FEI. Information on what the FEI Portal searches can be found on the [FEI Portal Frequently Asked Questions \(FAQ\)](#) or the "Help" button on the top right of this screen.

If you can't find an FEI using the FEI Portal for your firm or the firm you are representing, see the question "How can I request an FEI?" in the [FEI Portal Frequently Asked Questions \(FAQ\)](#) or the "Help" button on the top right of this screen.

Existing User

Email

Password

[Forgot Password](#)

Login

New User

Create Account

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the

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1단계 : OTC Drug 시설 등록시 필요한 정보

FEI가 뭐예요?

FEI FAQ

<https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=common.faq>

▼ How can I request an FEI?

If you can't find an FEI using the FEI Portal for your firm or the firm you are representing, you can request one by contacting feiportal@fda.hhs.gov and providing the following information:

1. The legal name of the firm being registered.
2. Are you representing the firm as an Agent (third party)?
3. Any alternate firm names, including those used for "doing business as" purposes.
4. The physical address of the firm being registered.
5. The designated mailing address for the firm being registered.
6. The name and contact information of the designated contact person at the facility being registered.
7. A comprehensive list of activities conducted at this specific location (e.g., drug manufacturing, food packaging, etc.).
8. Any registration numbers associated with other FDA Centers, if applicable.
9. Any former names the firm was known by.
10. Any previous addresses linked to the firm.

1단계 : OTC Drug 시설 등록시 필요한 정보

DUNS번호는 어디서 받아요?

- DUNS(Data Universal Numbering System, *데이터 통합 번호 설정 시스템) 번호
- Dun & Bradstreet(D&B)에서 제공하는 고유한 9자리 식별 번호입니다.
- <https://www.dnb.com/duns.html>
- 국제적으로 통용되는 사업자등록증번호와 같은 개념이라고 보시면 됩니다. 글로벌 비즈니스에서 강제적인 사항은 아니지만, '현재 운영되고 있는 사업자' 라는 것을 증명할 수 있는 방법이기도 합니다. 따라서, 미국 FDA는 등록 신청 업체에게 DUNS 번호 제출을 요구하는 것입니다.
- DUNS 번호는 특정 소재지(site)에 기반합니다. 따라서, 하나의 업체의 각기 다른 실제 장소(지사, 부서, 본사와 같이)에 DUNS 번호가 할당될 수 있습니다.
- DUNS 번호를 받는데 45일 이상 걸릴 수도 있습니다.

1단계 : OTC Drug 시설 등록시 필요한 정보

US Agent 는 어떤 역할을 해요?

21 CFR 207.69(b)

Registrants of foreign establishments must designate a single United States agent.

- **해외 시설**을 FDA에 등록할 때 **U.S. agent의 정보가 필요**합니다.
- U.S. agent 는 미국에 거주하거나 미국에 사업체를 유지하고 있으며 미국에 실제로 소재해야 합니다.
- 우편함, 자동 응답기나 자동 응답 서비스를 U.S. agent로 해서는 안 됩니다.
- U.S. agent의 역할은 아래와 같습니다.
 - ✓ FDA가 해외 제조업체와의 의사소통시 이를 돕는 역할
 - ✓ 미국 FDA가 해외 제조업체 혹은 수입업체에 대해 궁금한 사항이 있을 때 이에 대해 답변하는 역할
 - ✓ FDA가 해외 제조소에 대한 GMP 실사를 할 때 일정 잡는 것을 돕는 역할을 하게 됩니다.
- 즉, U.S. Agent는 반드시 미국에 소재해야 하며, 해외 시설을 대신해 미국 현지에서 FDA와 소통하는 역할을 담당합니다. 따라서 의사소통이 빠르고 원활하게 잘 되는 법인(또는 사람)을 U.S. Agent 로 지정하셔야 낭패가 없습니다.

1단계 : OTC Drug 시설 등록시 필요한 정보

Business Operation 가 뭐예요?

- OTC 의약품 시설(제조소) 등록과 관련하여 "Business Operation"(사업 운영)은 시설이나 제조소가 의약품과 관련하여 수행하는 특정 활동을 의미합니다
- 예) 분석, API(활성성분) 제조, 유통, 라벨, 제조, 포장, 회수, 재라벨, 재포장, 미국 대리인 등
- <https://www.fda.gov/industry/structured-product-labeling-resources/business-operation>

SPL Acceptable Term	Code
ANALYSIS	C25391
API/FDF ANALYTICAL TESTING	C101509
API MANUFACTURE	C82401
CLINICAL BIOEQUIVALENCE OR BIOAVAILABILITY STUDY	C101511
DISTRIBUTE	C201565
DISTRIBUTES DRUG PRODUCTS UNDER OWN PRIVATE LABEL	C73608
FDF MANUFACTURE	C101510
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	C112113
IMPORT	C73599
IN VITRO BIOEQUIVALENCE OR BIOANALYTICAL TESTING	C101512
LABEL	C84732
MANUFACTURE	C43360
MEDICATED ANIMAL FEED MANUFACTURE	C84635
OUTSOURCING ANIMAL DRUG COMPOUNDING	C122061
PACK	C84731
PARTICLE SIZE REDUCTION	C84386
POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION	C91403
RELABEL	C73607
REPACK	C73606
SALVAGE	C70827
SIP FOREIGN SELLER	C175317
STERILIZE	C84382
THIRD-PARTY LOGISTICS PROVIDER	C118412
TRANSFILL	C125710
UNITED STATES AGENT	C73330
WHOLESALE DRUG DISTRIBUTOR	C118411

1단계 : OTC Drug 시설 등록시 필요한 정보

Business Operation Qualifier 가 뭐예요?

- OTC 의약품 제조소 등록과 관련하여 "Business Operation Qualifier"(사업 운영 자격)는 사업 운영의 성격에 대해 추가적인 세부 정보를 제공합니다.
- 예) 계약제조, 모노그래프에 따라 인체용 OTC Drug 제조 등
- <https://www.fda.gov/industry/structured-product-labeling-resources/business-operation-qualifier>

SPL Acceptable Term	Code
Compounding from bulk ingredient	C112092
Compounding sterile products	C112094
Contract manufacturing	C132491
Contract manufacturing for human over-the-counter drug products produced under a monograph	C170729
Distributes human prescription drug products	C111077
Distributes human over-the-counter drug products	C111078
Intent to compound 506E (drug shortage) drugs	C112087
Manufactures animal prescription drug products	C114889
Manufactures animal over-the-counter drug products	C114891
Manufactures animal over-the-counter Type A medicated article drug products	C114892
Manufactures cosmetic products	C201560
Manufactures human over-the-counter drug products neither produced under an approved drug application nor under a monograph	C131710
Manufactures human over-the-counter drug products produced under a monograph	C131708
Manufactures human over-the-counter drug products produced under an approved drug application	C131709
Manufactures human prescription drug products	C106643
Manufactures Non-Generics	C101886
Manufactures veterinary feed directive Type A medicated article drug products	C114890
No intent to compound 506E (drug shortage) drugs	C112091
Not compounding from bulk ingredient	C112093
Not compounding sterile products	C112095
Transfills Medical Gas	C126091
Warehouses human prescription drug products	C123274

1단계 : OTC Drug 시설 등록 화면_Demo 영상 링크 안내

The screenshot shows the CDER Direct Electronic Submissions Portal. At the top, it says "CDER Direct Electronic Submissions Portal". Below that, a red banner states: "This application is for TESTING only. Any submissions made in this application are not officially recognized by the FDA. Use direct.fda.gov to make official submissions to FDA." The main content area is divided into two columns. The left column contains a "LOGIN" section with fields for "Username:" (containing "rsamuel2") and "Password:" (masked with dots). Below the password field is a link "Forgot your password?". A red "LOGIN" button is at the bottom of the login section. Below the login section is a "GETTING STARTED" section. It includes a paragraph about creating an account, a "WARNING" section with detailed privacy and security notices, a "Is your computer secure?" section, and a "Browser Compatibility" section listing supported browsers: Microsoft Edge, Firefox version 28 and above, Google Chrome, and Safari 10.0.1 and above. The right column contains a "QUICK LINKS" section with links to "Register With CDER Direct", "Resources", "Tutorials", "Help Desk", and "FAQs". Below that is a "NOTIFICATIONS" section.

CDER Direct
Electronic Submissions Portal

This application is for TESTING only. Any submissions made in this application are not officially recognized by the FDA. Use direct.fda.gov to make official submissions to FDA.

LOGIN

Username:
rsamuel2

Password:

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

☐ I Understand.

LOGIN [Forgot your password?](#)

QUICK LINKS

- [Register With CDER Direct](#)
- [Resources](#)
- [Tutorials](#)
- [Help Desk](#)
- [FAQs](#)

GETTING STARTED

To make submissions to FDA (e.g., Establishment Registration, Product Listing and Self-ID, etc.) you must first create an account. [Click here](#) to create a new account.

If you already have an account, enter your **Username** and **Password**.

WARNING: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

Is your computer secure? Before using FDA's Direct system, FDA strongly encourages you to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

Browser Compatibility: The CDER Direct portal currently works best with the following browsers:

- Microsoft Edge
- Firefox version 28 and above
- Google Chrome
- Safari 10.0.1 and above

NOTIFICATIONS

Electronic Drug Registration and Listing (eDRLS) Using CDER Direct – 2023 – Part 1

<https://www.youtube.com/watch?v=kCFqYcg1j6Y>

15:20 – How to Submit an Establishment Registration

1단계 : OTC Drug 시설 등록 화면_Demo 영상 링크 안내

The screenshot displays a web form for establishing a new facility. It is divided into five main sections:

- ESTABLISHMENT DETAILS:** Includes fields for Establishment Name (filled with "Corr7"), Establishment DUNS (filled with "987654321"), and Establishment FDI (empty).
- ESTABLISHMENT ADDRESS:** Includes fields for Country (dropdown menu showing "Canada"), Street Address (filled with "123 FDA Drive"), City (filled with "Hockley"), State/Province (filled with "Quebec"), and Postal Code (empty).
- ESTABLISHMENT CONTACT DETAILS:** Includes a checkbox "Same as Registrant Contact Details and Address" (checked), Contact Name (filled with "Troy"), Contact Email (filled with "troy@email.com"), Contact Phone (filled with "555-555-5555"), and Phone Extension (empty). A blue "Email" link is visible next to the phone field.
- ESTABLISHMENT CONTACT ADDRESS:** Includes fields for Country (dropdown menu showing "United States"), Street Address (filled with "123 FDA Drive"), City (filled with "DRLS"), State (dropdown menu showing "Select State"), and Postal Code (empty).
- U.S. AGENT:** Includes a field for Agent Name (filled with "Reg").


Electronic Drug Registration and Listing (eDRLS) Using CDER Direct – 2023 – Part 1

<https://www.youtube.com/watch?v=kCFqYcg1j6Y>


15:20 – How to Submit an Establishment Registration


1단계 : OTC Drug 시설 등록 제출 후 상태값

1. 시설 등록 제출
2. "Status(상태)" 값이 "Awaiting Acceptance"로 되어 있음
3. Validation Process 를 거친 후 (예 : DUNS 넘버 검증)
4. "Status(상태)" 값이 Submission Accepted 또는 Submission Failed 으로 바뀜

 U.S. Department of Health & Human Services

Welcome DRUGSRUS - DRUGSRUS | Logout

 **CDER Direct**
Electronic Submissions Portal

Draft deleted successfully. 


Home

SUBMISSIONS
[\(ADD SUBMISSION TYPE\)](#)
Establishment Registration
Product Listing and Certification


MANAGE ACCOUNT
Edit User Profile
Manage Users

COVID-19

ALL SUBMISSIONS
For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic drug registration and listing, contact eDRLS@fda.hhs.gov.



GO ACTIONS

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION ACCEPTED	ca643fb2-7c35-8131-e053-2995af0a3854	caf39dd3-8445-c128-e053-2995af0a804e	cd4865173209.7824601593@direct	3	ESTABLISHMENT DE-REGISTRATION	Vikas Arora	01-SEP-2021 13:51:09	
SUBMISSION ACCEPTED	ca5028b4-e845-0b05-e053-2a95af0af82a	caf1dcf3-3438-14f5-e053-2a95af0ad3d1	cd6253017498.9436017825@direct	3	ESTABLISHMENT DE-REGISTRATION	Vikas Arora	01-SEP-2021 11:45:12	
SUBMISSION ACCEPTED	ca643fb2-7c35-8131-e053-2995af0a3854	ca7e5104-3203-5f89-e053-2995af0ac7f5	cd6183047925.3257091648@direct	2	ESTABLISHMENT REGISTRATION	Vikas Arora	27-AUG-2021 13:27:03	
SUBMISSION ACCEPTED	ca5028b4-e845-0b05-e053-2a95af0af82a	ca7e45ff-eef0-738a-e053-2a95af0a0b58	cd4012596387.7438216905@direct	2	ESTABLISHMENT REGISTRATION	Vikas Arora	27-AUG-2021 13:27:03	
SUBMISSION ACCEPTED	ca5028b4-e845-0b05-e053-2a95af0af82a	ca5028b4-e846-0b05-e053-2a95af0af82a	cd1480697532.3674218905@direct	1	ESTABLISHMENT REGISTRATION	Vikas Arora	26-AUG-2021 09:56:49	

Contact Help Desk

1단계 : OTC Drug 시설 등록 갱신(업데이트)

매년 10월 1일부터 12월 31일까지 등록 갱신을 해야 합니다.

- 기존에 제출한 정보에 대한 변경사항이 없는 경우 **변경 없음 보고(No Change Notification)**를 제출
- **10월 1일부터 12월 31일 사이에 최초 등록 또는 등록 갱신을 한 경우, 해당 등록은 다음 해의 말일까지 유효합니다. 이 기간 이외에 제출된 등록은 현재 연도의 말일 이후에 등록 만료일이 연장되지 않습니다.**

다음이 변경될 때 시설 등록을 업데이트해야 합니다. (변경사항이 발생한 날로부터 30일 이내에)



- Change in Contact Information
- Change in Company Name
- Change in Establishment Address
- Change in Business Operation
- Changes in Business Operation Qualifier
- Change in U.S. Agent

미국으로 선적되기 전에

- 수입사 정보 변경
- 새로운 수입사 추가

시설 등록 취소

- 회사가 문을 닫은 경우
- 더 이상 의약품 제조 활동에 관여하지 않는 경우

예시 1:

2024년 10월 1일에 등록 접수된 경우, 해당 등록은 2025년 12월 31일까지 유효합니다.

예시 2:

2024년 9월 30일에 등록이 접수된 경우, 해당 등록은 2024년 12월 31일까지 유효합니다.

등록을 2025년 12월 31일까지 유지하려면 2024년 10월 1일부터 12월 31일 사이에 업데이트된 제조소 등록을 제출해야 합니다.

◆ Document Types for Establishment Registration

- Establishment Registration
- No Change Notification
- Establishment De-Registration
- Out of Business Notification

1단계 : OTC Drug 시설 등록 면제, 시설 정보 공개

시설등록이 면제되는 경우는?

◆ 오직 다음의 활동만 수행하는 경우:

- 연구, 교육 또는 화학 분석용으로만 사용되며 판매용이 아닌 의약품 제조하는 경우
- 의약품의 성분이 되는 부형제, 착색제, 향료, 유화제, 윤활제, 방부제 또는 용제 등 무해한 비활성 성분을 제조하는 경우

등록된 의약품 시설 정보 공개

◆ FDA에서는 등록된 의약품 시설에 대한 정보(회사명, FEI, DUNS, 사업 운영형태, 주소, 시설 등록 유효기간)를 공개하고 있음

Drug Establishments Current Registration Site

<https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>

The screenshot shows the FDA's Drug Establishments Current Registration Site. The header includes the FDA logo and 'U.S. FOOD & DRUG ADMINISTRATION'. A search bar for 'Search FDA.gov' and a 'Menu' icon are on the right. Below the header, a breadcrumb trail shows 'Home' > 'Drug Databases' > 'DECRS'. Social media sharing options for Facebook, Twitter, LinkedIn, Email, and Print are also present. The main heading is 'Drug Establishments Current Registration Site'. Below this, a red asterisk indicates a '*Required Field'. The section is titled 'Search the database'. There is a label 'Search for Firm Name: *' above a text input field containing the placeholder 'Search For Firm Name'. At the bottom of the search area are two buttons: 'SUBMIT' and 'CLEAR'.

2단계 : NDC 레이블러 코드 요청

각 제품별로 NDC(National Drug Code) 번호가 부여됩니다.

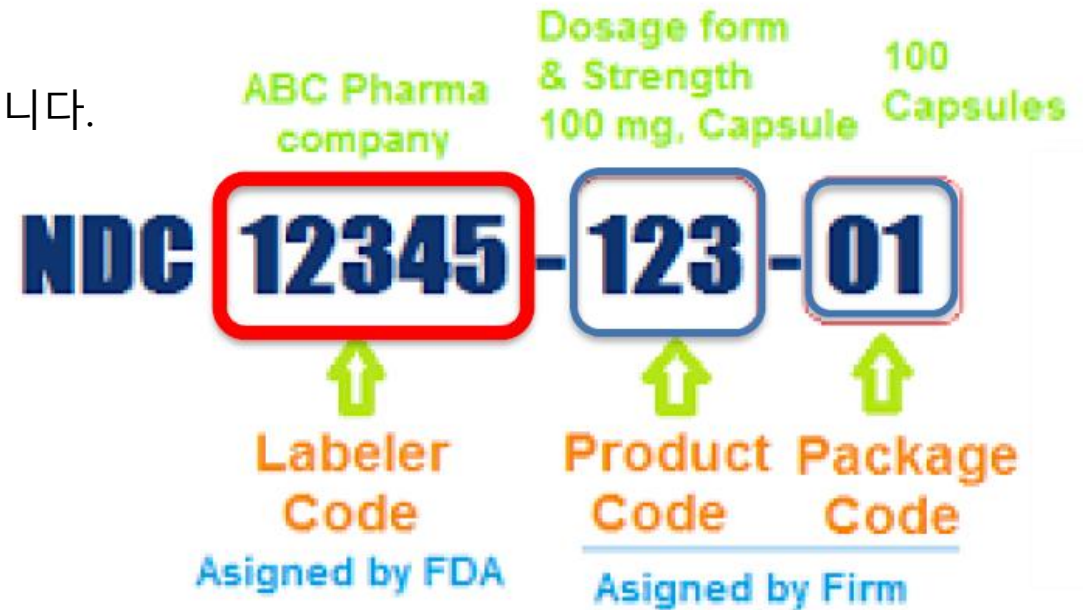
NDC 번호는 3개의 세그먼트로 구성되어 있습니다.

첫 번째 세그먼트: 레이블러 코드

두 번째 세그먼트: 제품 코드

세 번째 세그먼트: 패키지 코드

예시: 12345-123-01



① 레이블러 코드(labeler code): FDA로부터 부여받음

- Labeler란 해당 Drug의 제조업자(재포장 또는 재라벨을 포함) 또는 유통업자(자기 상표)를 말하며 FDA한테 부여받은 번호임

② 제품 코드(product code): 회사에서 부여하면 됨

- product code는 함량(specific strength), 용량(dosage form), 포물레이션(formulation for a particular firm)을 확인할 수 있게 회사에서 부여한 번호임

③ 패키지 코드 (package code): 회사에서 부여하면 됨

- package code는 포장 단위(variations of packaging), 예를 들면 10ml 인지, 20ml 인지, 50ml 인지 나타내며, 회사에서 부여하면 됨

2단계 : NDC 레이블러 코드 요청

아래 사항을 포함한 Labeler Code SPL document를 FDA에 제출하여 NDC labeler code 부여를 요청하면 됩니다.

아래 링크에서 FDA 강의 영상 [54:08](#) – CDER Direct Labeler Code Request Demo 참고

<https://www.youtube.com/watch?v=kCFqYcg1j6Y>

[54:08](#) – CDER Direct Labeler Code Request Demo

Company Name 회사명	DUNS number DUNS 번호	Establishment Address 시설 주소
Registrant Contact Information 등록자 연락처 정보	Business Operation & Qualifier 비즈니스 운영 & 자격자	U.S. Agent Information 미국 대리인 정보

- Labeler Details (Name, DUNS)
- Labeler Contact Details (Name, Email, Phone, Extensions)
- Labeler Contact Address (Country, Street Address, City, State, Postal Code)
- Additional Labeler Details (Country, State Address, City, State, Postal Code)
- U.S. Agent (Name, DUNS, Email, Phone, Extension)
- Business Operations
- Business Operation Qualifier

2단계 : NDC 레이블러 코드 요청

Requesting a labeler code

CDER Direct

https://direct.fda.gov/apex/f?p=100:LOGIN_DESKTOP

Home NDC Labeler Code Request SPL Submission

SUBMIT SPL SAVE AS DRAFT SAVE AND VALIDATE DELETE << RETURN

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Labeler Code Request submission form. Red asterisk indicate required fields.

HEADER DETAILS

Document Type: * NDC LABELER CODE REQUEST

Set ID: * 05d52a4b-6a66-0828-e063-6b94af0ae673 [Generate New](#) Version Number: * 1

Root ID: * 05d52a4b-6a67-0828-e063-6b94af0ae673 [Generate New](#) Effective Date: * 09-20-2023

LABELER DETAILS

Labeler Name: * WonderPharma Labeler Code: *

Labeler DUNS: * 123456789

LABELER CONTACT DETAILS

Contact Name: * John Doe

Contact Email: * Wonderpharma@Wonderpharma.com

Contact Phone: * 555-876-5309 [Format](#)

Phone Extension: *

LABELER CONTACT ADDRESS

Country: * United States

Street Address: * 123 Main St

City: * Herndon

State: * Virginia

Postal Code: * 20171

2단계 : NDC 레이블러 코드 요청

— ADDITIONAL LABELER DETAILS (Optional - Including the following information will expedite the processing of your request)

LABELER ADDRESS		U.S. AGENT	
<input type="checkbox"/> Same as Labeler Contact Address		Agent Name:	<input type="text"/>
Country: *	<input type="text" value="Select Country--"/>	Agent DUNS:	<input type="text"/>
Street Address: *	<input type="text"/>	Agent Email:	<input type="text"/>
City: *	<input type="text"/>	Agent Phone:	<input type="text"/>
State/Province:	<input type="text"/>	Phone Extension:	<input type="text"/>
Postal Code:	<input type="text"/>		<input type="text"/>

— BUSINESS OPERATION(S)

[ADD BUSINESS OPERATION](#)

EDIT	DELETE	BUSINESS OPERATION	QUALIFIER
<input checked="" type="checkbox"/>	<input type="checkbox"/>	REFACE	DISTRIBUTES HUMAN PRESCRIPTION DRUG PRODUCTS

1 of 1

- Labeler Details (Name, DUNS)
- Labeler Contact Details (Name, Email, Phone, Extensions)
- Labeler Contact Address (Country, Street Address, City, State, Postal Code)
- Additional Labeler Details (Country, Street Address, City, State, Postal Code)
- U.S. Agent (Name, DUNS, Email, Phone, Extension)
- Business Operations
- Business Operation Qualifier

2단계 : NDC 레이블러 코드 요청

Completing a labeler code process

st
ssions Portal

Home > NDC Labeler Code Request

SUBMISSIONS
(ADD SUBMISSION TYPE)

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

NDC Reservation

NDC LABELER CODE REQUEST

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic drug registration and listing, contact eDRLS@fda.hhs.gov.

Q

GO

ACTIONS

CREATE NEW / UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER	LAST MODIFIED DATE	REQUEST PROGRESS	
AWAITING ACCEPTANCE	05d52a4b-6a66-0828-e063-6b94af0ae673	05d52a4b-6a67-0828-e063-6b94af0ae673	cd972684315.8074651392@direct	1	NDC LABELER CODE REQUEST	123456789	WonderPharma	Soo Jin Park	21-SEP-2023 18:16:59	-	-
SUBMISSION FAILED	84312c4a-d284-bbfc-e053-2995af0a28b9	05d34713-2d99-c411-e063-6a94af0ac297	cd8726503491.6493527801@direct	3	NDC LABELER CODE REQUEST	123456789	Wonderpharma	Soo Jin Park	20-SEP-2023 20:11:08	-	-
SUBMISSION ACCEPTED	84312c4a-d284-bbfc-e053-2995af0a28b9	05cb4e85-a2f7-3929-e063-6b94af0adfc5	cd4378569120.9572306184@direct	2	NDC LABELER CODE REQUEST	123456789	Wonderpharma	Soo Jin Park	20-SEP-2023 09:33:09	-	-
VALIDATION FAILURE	05ca5a78-12d0-73b5-e063-6a94af0ad25f	05ca5a78-12d1-73b5-e063-6a94af0ad25f		1	NDC LABELER CODE REQUEST	987654321	Drug Name	Soo Jin Park	20-SEP-2023 09:06:08	-	-

1 - 4

2단계 : NDC 레이블러 코드 요청

Confirm labeler code assignment

Labeler Code - Assigned



FDA will send an email to the contact email on the request with the assigned number.
eDRLS - Electronic Drug Registration & Listing System

Current Date: 31-August-2023

Labeler DUNS: 000000000

Labeler Name: A1 Drug Company

Labeler Code Assigned: 00000

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

2단계 : NDC 레이블러 코드 업데이트

Updating labeler contact or address

아래 항목에 변경사항이 있을 때 레이블러 코드 정보를 30일 이내에 업데이트 해야합니다 .

- 회사명
- DUNS
- 주소
- 지정된 등록자(Labeler Contact) 연락처 정보
- 미국 대리인(U.S. Agent) 정보
- Business Operations, Business Operation Qualifier

3단계 : OTC Drug 제품 등록 (Drug Listing)

의약품 등록 (Drug Listing)에 필요한 정보

National Drug Code
(NDC) Number

NDC 번호

Product Name

제품명

Dosage Form

제형

Route of Administration

투여 경로

Ingredients

성분

Packaging Information

패키징 정보

Manufacturers'
Information

제조사 정보

Labeling

라벨링

3단계 : OTC Drug 제품 등록 갱신(업데이트)

- 아래 사항의 변경이 있을 경우, 의약품 등록(Drug Listing)을 업데이트 해야 합니다.
- 매년 10월 1일과 12월 31일 사이에 업데이트 하거나, '변경 사항이 없음'을 제출해야 합니다.
- 등록되지 않은 의약품은 미국으로 수입시 억류됩니다.

제조사 또는 레이블러의
회사명 또는 DUNS 번호

Company Name
or DUNS
number of
Manufacturer
or Labeler

Inactive
Ingredients

비활성 성분

아트워크
(제품 패키지
도안)

Artwork

No longer being
marketed

더 이상 판매되지 않음

3단계 : OTC Drug 제품 정보 공개

FDA에 등록된(Drug listing 된) OTC Drug는 아래 사이트에서 검색할 수 있습니다.

Dailymed 웹사이트 <https://dailymed.nlm.nih.gov/dailymed/>

NIH NATIONAL LIBRARY OF MEDICINE

REPORT ADVERSE EVENTS | RECALLS

DAILYMED

ALL DRUGS | HUMAN DRUGS | ANIMAL DRUGS

Enter drug, NDC code, drug class, or Set ID

MORE WAYS TO SEARCH: [ADVANCED SEARCH](#) [BROWSE DRUG CLASSES](#) [LABELING ARCHIVES](#)

The DailyMed database contains **151309** labeling submitted to the **Food and Drug Administration (FDA)** by companies. DailyMed does not contain a complete listing of labeling for FDA-regulated products (e.g., labeling that is not submitted to the FDA). See [ABOUT DAILYMED](#) for more information.

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NEWS

[DailyMed Announcements](#)

Posted: September 15, 2021

The RxImage API will cease operation on December 31, 2021. DailyMed will be removing pill images provided by the RxImage API on October 31, 2021. Pill images submitted by labelers with their

FDA RESOURCES

[SPL, Other Prescription Drug Labeling Resources, and Guidances](#)

- [FDA's Structured Product Labeling Resources](#)
- [FDA's Prescription Drug Labeling Resources](#)
- [FDA's Drug Guidances](#)
- [Risk Evaluation and Mitigation Strategies \(REMS\)](#)

- FDA가 시장 사후 감독시, 다른 정보가 없더라도, 라벨링에 있는 NDC(National Drug Code) 번호를 보면, DailyMed 사이트에서 검색하여 이미 등록된 정보를 확인할 수 있음
- NDC 디렉토리에 수재되어 있다는 것이 제조업자 및 시장에 출시된 해당 제품에 대한 승인을 의미하는 것은 아님

3단계 : OTC Drug 제품 정보 공개

예시 | <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8e294a61-97e2-4df8-8a59-7cec12c6f016>



ALL DRUGS | HUMAN DRUGS | ANIMAL DRUGS | MORE WAYS TO SEARCH ▼

Enter drug, NDC code, drug class, or Set ID

HOME | NEWS | FDA RESOURCES | NLN SPL RESOURCES | APPLICATION DEVELOPMENT SUPPORT | HELP

LABEL: LOREAL PARIS AGE PERFECT CELL RENEWAL DAY MOISTURIZER BROAD SPECTRUM SPF 25 SUNSCREEN- avobenzone, homosalate, octisalate... [view full title](#)

LABEL RSS

VIEW PACKAGE PHOTOS



SAFETY

[Report Adverse Events](#)

[FDA Safety Recalls](#)

[Presence in Breast Milk](#)

RELATED RESOURCES

[Medline Plus](#)

[Clinical Trials](#)

[+ PubMed](#)

[Biochemical Data Summary](#)

MORE INFO FOR THIS DRUG

[View Labeling Archives](#)

[RxNorm](#)

[Get Label RSS Feed](#)

[View NDC Code\(s\) NEW!](#)

[NDC Code\(s\): 49967-036-01, 49967-036-02](#)
Packager: L'Oreal USA Products Inc
Category: HUMAN OTC DRUG LABEL
DEA Schedule: None

DRUG LABEL INFORMATION

Updated December 29, 2023

If you are a consumer or patient please visit [this version](#).

DOWNLOAD DRUG LABEL INFO: [PDF](#) | [XML](#) | [Image](#) | [OFFICIAL LABEL \(PRINTER FRIENDLY\)](#) [Image](#)

[VIEW ALL SECTIONS](#)

ACTIVE INGREDIENTS

Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 7%

PURPOSE

Sunscreen

USES

- helps prevent sunburn - if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

WARNINGS

For external use only

DO NOT USE

on damaged or broken skin

WHEN USING THIS PRODUCT

keep out of eyes. Rinse with water to remove.

- +


 STOP USE AND ASK A DOCTOR IF
rash occurs
- +

 KEEP OUT OF REACH OF CHILDREN.
If swallowed, get medical help or contact a Poison Control Center right away.
- +

 DIRECTIONS
For sunscreen use: • apply liberally 15 minutes before sun exposure - • reapply at least every 2 hours - • use a water resistant sunscreen if swimming or sweating - • Sun Protection Measures. Spending ...
- +

 OTHER INFORMATION
protect the product in this container from excessive heat and direct sun
- +

 INACTIVE INGREDIENTS
water, glycerin, alcohol denat., hydrogenated polyisobutene, bis-PEG-18 methyl ether dimethyl silane, dimethicone, cetearyl alcohol, PEG-100 stearate, PEG-20, petrolatum, butyrospermum parkii ...
- +

 PRINCIPAL DISPLAY PANEL

...
- +

 INGREDIENTS AND APPEARANCE
Product Information

[VIEW ALL SECTIONS](#)

OTC Monograph Drug User Fee Program (OTC 모노그래프 사용자 수수료 프로그램)

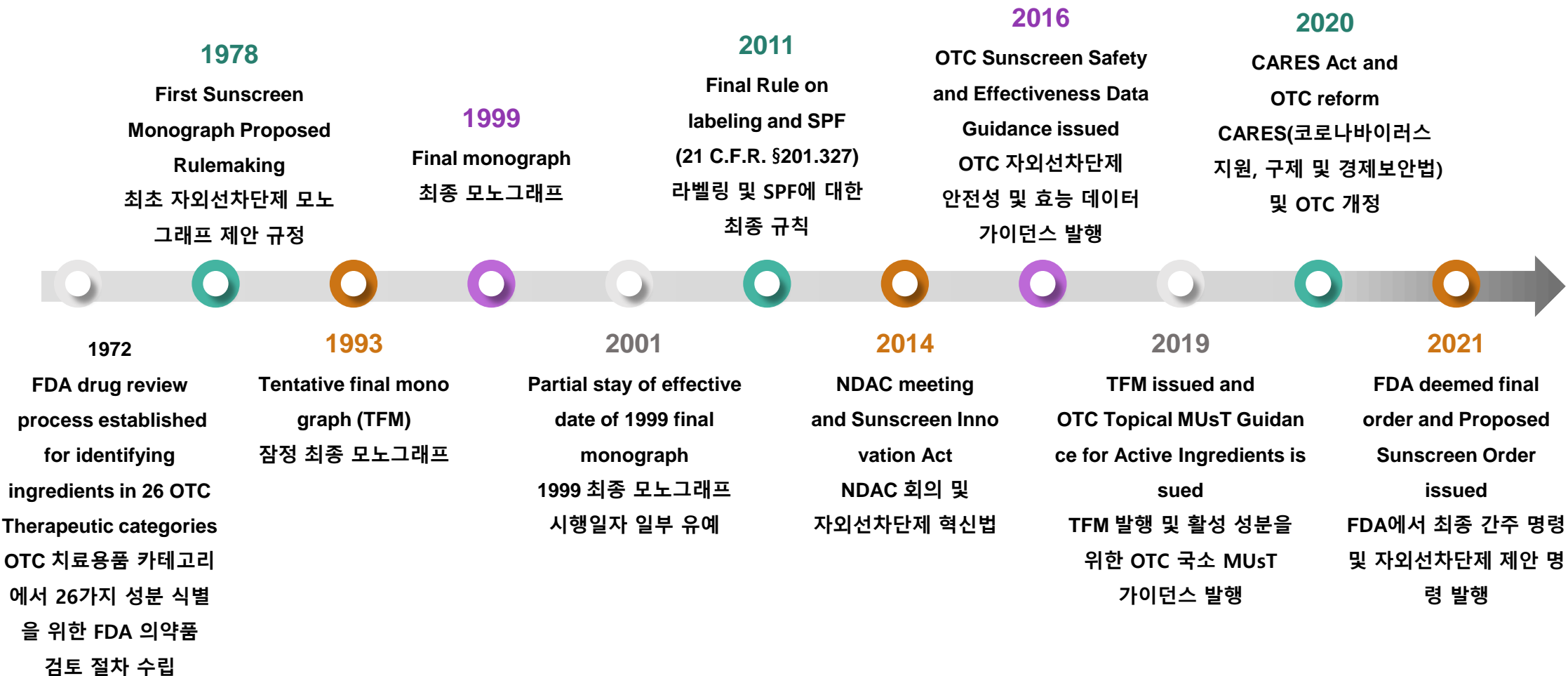
2024 회계연도 수수료, 2023년 10월 1일부터 2024년 9월 30일까지 적용

구분	2024회계연도 수수료 요율
Monograph Drug Facility (MDF) Facility Fee OTC 모노그래프 의약품 시설 수수료	\$ 34,166 (한화 약 4,800만원)
Contract Manufacturing Organization (CMO) Facility Fee 계약제조업체 시설 수수료	\$ 22,777 (한화 약 3,200만원)

※ 2025 회계연도 수수료는 2025년 3월에 설정될 예정이며, 납부기한은 2025년 6월 입니다.

- OTC 모노그래프 의약품 시설(이하 '**MDF**')이란 OTC 모노그래프 의약품의 최종 제형을 제조 또는 가공하는 일에 관여하며 기타 필수 요건을 충족하는 해외 또는 국내 기업 또는 기타 주체를 말합니다. FD&C법 섹션 744L(10) 참고.
- 계약제조업체(이하 '**CMO**') 시설이란 OTC 모노그래프 의약품 시설로서 그 시설의 소유주, 소유주의 계열사, 또는 시설의 계열사가 해당 시설에서 생산된 OTC 모노그래프 의약품을 미국 내 도매업자, 소매업자, 또는 소비자에게 직접 판매하지 않는 곳을 말합니다. FD&C법 섹션 744L(2) 참고.

미국의 자외선차단제 규제 히스토리



OTC Monograph M020 | Published 09/24/2021

Title: Sunscreen Drug Products for Over-the-Counter Human Use

https://dps.fda.gov/omuf/monographsearch/monograph_m020

자외선차단제 라벨링

CFR - Code of Federal Regulations Title 21
Sec. 352.52 Labeling of sunscreen drug products.
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=352.52>

제조사, 유통업체 또는
포장업체:
회사 이름 및 주소

제품 식별명

SPF, 내수성, 및
브로드 스펙트럼

내용물의 실증량

Statement of Identity

SPF, Water Resistance,
and Broad Spectrum
Declarations

Net Quantity of
Contents

Manufacturer,
Distributor, or Packer:
corporate name and
address

Domestic U.S. phone
number or mailing
address for serious
adverse event reporting

Lot Number

Expiration Date

Drug Facts Panel

심각한 부작용 보고를
위한 미국 국내
전화번호 또는
우편 주소

로트 넘버

유효 기한

드러그 팩트 패널

자외선차단제 라벨링

제품 식별명(Statement of Identity : SOI)

Must include:

- Established name of drug (if any)
- General pharmacological category(ies) or principal intended action
- Mixtures of drugs with no established name may satisfy the requirement with a prominent display of the pharmacological category(ies) or principal intended action

Sunscreens must include “sunscreen” as part of the SOI

Must be placed:

- On the Principal Display Panel (PDP) – usually the front of the package
- In boldface type, parallel to the base of the package
- In a type size reasonably related to the most prominent text on the label

다음은 반드시 포함해야 합니다. :

- 의약품의 일반명 (있는 경우)
- 일반 약리학적 범주 또는 주요 의도된 작용
- 일반명이 없는 의약품의 혼합물은 약리학적 범주 또는 주요 의도된 작용을 눈에 띄게 표시하여 요구 사항을 충족할 수 있습니다.

자외선 차단제는 SOI(제품 식별명)에 반드시 “sunscreen”을 포함해야 합니다.

다음에 위치해야 합니다.:

- 주 디스플레이 패널(PDP) – 일반적으로 패키지 전면
- 볼드체로 패키지 바닥과 평행
- 레이블에서 가장 눈에 띄는 텍스트와 합리적으로 관련된 활자 크기로

자외선차단제 라벨링

SPF 지수, 내수성 및 브로드 스펙트럼(SPF Value, Water Resistance and Broad Spectrum)

- Sunscreens must include a Sun Protection Factor (SPF) value, determined according to the testing procedures found in the final order.
- Final order does not include a maximum labeled value
- Previous proposed rule (2011) had limited maximum labeled value to "50+"
- Proposed order limits maximum labeled value to "60+"
- Products that pass the FDA water resistance testing procedures (40 or 80 minutes) may declare it on the label.
- Products with an SPF ≥ 15 , that also pass the testing procedure for "broad spectrum" found in the final order may include "broad spectrum" on the labeling. These products may also make claims about prevention of skin cancer.
- 자외선 차단제는 최종 명령에 있는 테스트 절차에 따라 결정된 자외선 차단 지수(SPF) 값을 포함해야 합니다.
- 최종 명령에서는 최대 표시 값을 지정하고 있지 않습니다.
- 이전에 제안된 규칙(2011년)은 최대 표시 값을 "50+"로 제한했습니다.
- 제안된 명령은 최대 표시값을 "60+"로 제한하고 있습니다.
- FDA 내수성 테스트 절차(40분 또는 80분)를 통과한 제품은 라벨에 "내수성(water resistance)"을 표시할 수 있습니다.
- SPF ≥ 15 인 제품으로 최종 명령에 명시된 "브로드 스펙트럼"에 대한 테스트 절차를 통과하면 라벨에 "broad spectrum"이 포함될 수 있습니다. 이러한 제품은 또한 피부암 예방에 대한 클레임(효능효과 주장)을 할 수 있습니다.

자외선차단제 라벨링

내용물의 실중량 (Net Quantity of Contents)

- May be declared by solid/viscous measure, liquid measure, numerical count, unit strength, linear measure or area, depending on the dosage form or type of drug
- Must include avoirdupois and metric measure, when applicable
- Declarations of solid measure must include "Net Weight" or "Net Wt."
- Must appear in the bottom 30% of the PDP in a type size that is based upon the area of the PDP
- 의약품의 종류 또는 제형에 따라 고체/점성 측정, 액체 측정, 수치, 단위 용량, 선형 측정 또는 면적으로 표시될 수 있습니다.
- 해당되는 경우 voirdupois (파운드 질량) 및 미터법을 포함해야 합니다.
- 고체의 경우, "Net Weight" 또는 "Net Wt." 를 표시합니다.
- PDP의 면적을 기준으로 한 활자 크기로 PDP의 하위 30%에 표시되어야 합니다.

자외선차단제 라벨링

제조사, 포장업체, 또는 유통업체 (Manufacturer, Packer, or Distributor)

- Label must include the actual corporate name and full address (no P.O. boxes) of the manufacturer, distributor or packer
- Entities that are not the manufacturer must include a descriptive phrase such as “packed by” or “manufactured for”
- Street address may be omitted if found in a current city directory or telephone directory
- 라벨에는 제조사, 유통업체 또는 포장업체의 실제 회사 이름과 전체 주소(사서함은 안됨)가 포함되어야 합니다.
- 제조사가 아닌 기업은 "packed by" 또는 "manufactured for"와 같은 설명 문구를 포함해야 합니다.
- 현재 도시 디렉토리 또는 전화 번호부에 있는 경우 거리 주소를 생략할 수 있습니다.

자외선차단제 라벨링

미국 주소 또는 전화번호 (U.S. Address or Phone Number)

- Drug label must include a domestic U.S. phone number (including area code) or full mailing address to which a consumer can report a serious adverse event
- Address or phone number must lead to a “responsible person” who must submit a report of the event to FDA within 15 business days of receipt
- FDA recommends (but does not require) a clear statement be included such as “To report a serious adverse event, contact...”
- 의약품 라벨에는 소비자가 심각한 이상 사례(심각한 부작용)을 보고할 수 있는 미국 국내 전화번호(지역 번호 포함) 또는 전체 우편 주소가 포함되어 있어야 합니다.
- 주소 또는 전화번호는 접수 후 영업일 기준 15일 이내에 FDA에 부작용 보고서를 제출해야 하는 "책임자"로 연결되어야 합니다.
- FDA는 "심각한 이상 사례를 보고하려면 연락하십시오..."와 같은 명확한 문구를 포함할 것을 권장합니다. (그러나 요구하지는 않습니다.)

자외선차단제 라벨링

롯트 번호 및 유효 기한 (Lot Number and Expiration Date)

- Lot number is defined as “any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.”
- Expiration date must ensure that the drug meets applicable standards of identity, strength, quality, and purity at the time of use
 - Determined by appropriate stability testing according to 21 CFR 211.166
 - Should appear on both the immediate package and outer container
 - Drugs with no dosage limitations that are stable for 3 years are exempt
- 로트 번호는 “의약품 또는 기타 물질의 유통 또는 로트의 제조, 가공, 포장, 보관 및 유통의 전체 이력을 확인할 수 있는 문자, 숫자 또는 기호의 고유한 조합 또는 이들의 조합”으로 정의됩니다.
- 유효 기한은 해당 의약품이 사용 당시의 동일성, 용량, 품질 및 순도에 대한 해당 표준을 충족하는지를 보증해야 합니다.
 - 21 CFR 211.166에 따라 적절한 안정성 테스트에 의해 결정됩니다.
 - 직접 포장(1차 포장)과 외부 용기 모두에 표시해야 합니다.
 - 3년간 안정한 용량제한이 없는 의약품은 면제됩니다.

자외선차단제 라벨링 – Drug Facts Panel

Active ingredient(s) / Purpose 활성성분/목적

Uses 용도

Warnings 경고문구

Directions

지시사항

Other information 기타 정보

Inactive ingredients 비활성 성분

Questions (optional) 문의처(선택사항)

<i>Drug Facts</i>	
<i>Active ingredient (in each dosage unit)</i>	<i>Purpose</i>
XXXXXXXXXXXXXXXXXXXX mg.....	XXXXXXXXXXXXX
<i>Uses</i>	
■ XXXXXXXXXXXXXXXXX ■ XXXXXXXXXXXXXXXXX	
<i>Warnings</i>	
Do not use XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
Ask a doctor before use if you have	
■ XXXXXXXXXXXXXXXXX ■ XXXXXXXXXXXXXXXXX	
Ask a doctor or pharmacist before use if you are XXXXXXXXXXXXXXXXX	
When using this product	
■ XXXXXXXXXXXXXXXXX ■ XXXXXXXXXXXXXXXXX	
Stop use and ask a doctor if	
■ XXXXXXXXXXXXXXXXX ■ XXXXXXXXXXXXXXXXX	
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	

Drug Facts (continued)
Directions ■ xxxxxxxxxxxxxxxx ■ xxxxxxxxxxxxxxxx
Other information ■ xxxxxxxxxxxxxxxx ■ xxxxxxxxxxxxxxxx
Inactive ingredients xxxxxxxxxxxxxxxx
Questions? 123-555-1234

자외선차단제 라벨링 – Drug Facts Panel

Drug Facts 예시

브로드 스펙트럼

SPF ≥ 15

내수성 40 분

Drug Facts

Active ingredients

Titanium dioxide 8% }
Zinc oxide 16% } Sunscreen

Purpose

Uses

- helps prevent sunburn
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use ■ on damaged or broken skin

When using this product ■ keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if ■ rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m.-2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
- children under 6 months of age: Ask a doctor

Other information

- protect the product in this container from excessive heat and direct sun
- store below 90°F / 30°C

Inactive ingredients

Water, soybean (*Glycine max*) oil, hydroxyethylcellulose, xanthan gum, glyceryl monostearate, barium sulfate, cetearyl alcohol, glycerin, petrolatum, African oil palm (*Elaeis guineensis*), sodium benzoate, potassium sorbate, fragrance, watermelon (*Citrullus lanatus*) oil, jojoba (*Simmondsia chinensis*) oil, argan (*Argania spinosa*) oil, aloe vera extract, vanilla (*Vanilla planifolia*) oil, ascorbic acid, retinyl palmitate, tocopherol acetate

자외선차단제 라벨링 예시 1

Drug Facts

Active ingredients

Azobenzene 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 7%	Sunscreen

Purpose

Uses

- helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

- For external use only
- Do not use on damaged or broken skin
- When using this product keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash occurs
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- For sunscreen use:
- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - children under 6 months of age: Ask a doctor

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients water, glycerin, dimethicone, silica, PEG-100 stearate, glyceryl stearate, octyldodecanol, behenyl alcohol, butyrospermum peridi (shea) butter, copernicia cerifera (carnauba) wax, saccharomyces/xylinum/black tea ferment, stearic acid, phenoxethanol, palmitic acid, dimethyl isosorbide, ammonium polyacryloyldimethyl taurate, hydroxyacetophenone, dicaprylyl carbonate, steareth-100, capryloyl salicylic acid, caprylyl glycol, xanthan gum, dimethicone/vinyl dimethicone crosspolymer, acrylamide/sodium

Drug Facts (continued)

acryloyldimethyl taurate copolymer, disodium EDTA, isohexadecane, tocopherol, fragrance, neohesperidin dihydrochalcone, adenosine, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, poly C10-30 alkyl acrylate, myristic acid, polysorbate 80, hydroxyethylcellulose, sorbitan oleate, sodium citrate, citric acid, hexyl cinnamal, yellow 5, benzyl alcohol, hydroxycitronellal, benzyl salicylate, linalool, citronellol, potassium sorbate, limonene, geraniol, alpha-isomethyl ionone, red 4, blue

FORMULA # 9171514 F.I.L. #D273003/1 PAT: PATENTS.LOREALPARIS.COM

REVEAL MILLIONS OF NEW SURFACE CELLS. VISIBLY YOUNGER SKIN

Broad Spectrum SPF 25 sunscreen moisturizer with: **ANTIOXIDANT RECOVERY COMPLEX**

Patented antioxidant from bitter orange + **Vitamin E** naturally found in skin.

Support skin's natural renewal process. Recover skin's antioxidants and helps defend against daily aggressions.

VISIBLE RESULTS

- Immediately** Skin feels smoother, more supple.
- In 1 week** Skin looks replumped and radiant.
- In 4 weeks** Skin appears revitalized. Wrinkles are visibly smoothed. Skin feels firmer and more dense.

- ✓ All day hydration
- ✓ Does not clog pores
- ✓ Non-greasy

L'ORÉAL®
PARIS

NEW

BROAD SPECTRUM
SPF 25
SUNSCREEN

AGE PERFECT®
CELL RENEWAL*

ANTI-AGING™
MOISTURIZER

Reveal millions of new skin cells
Smooth wrinkles, firm, revitalize

ANTIOXIDANT RECOVERY COMPLEX

*based on skin cell exfoliation
**when used as directed with other sun protection measures. NET WT. 1.7 OZ. (48g)

L'ORÉAL PARIS SKINCARE COMMITMENTS



Every product is **extensively tested for safety** with a minimum of 400 applications, under the **guidance of dermatologists**.



Every product benefit is tested by unbiased **independent third parties**.

「DERMATOLOGIST TESTED
SUITABLE FOR SENSITIVE SKIN」



Questions or comments?
L'ORÉAL USA, Inc., 10 Hudson Yards,
New York, NY 10001 1-800-322-2036
Made in USA of US and/or Imported Ingredients

ACTUAL SIZE

L'ORÉAL PARIS SKINCARE COMMITMENTS

Every product is extensively tested for safety with a minimum of 400 applications, under the guidance of dermatologists.

Every product benefit is tested by unbiased independent third parties.

VALIDATED IN PARTNERSHIP WITH AN ADVISORY PANEL OF DERMATOLOGISTS THROUGH:

Thorough review of test protocols and results

Comprehensive ingredient screening for efficacy, safety & tolerance

DERMATOLOGIST TESTED SUITABLE FOR SENSITIVE SKIN

- ✓ Absorbs quickly
- ✓ Non-greasy
- ✓ No white cast on any skin tones

ALLERGY TESTED FRAGRANCE FREE
PARABEN FREE DYE FREE MINERAL OIL FREE



By using a FSC®-certified paperboard for this package, L'ORÉAL PARIS supports forest management that respects people and nature.

L'ORÉAL PARIS

NEW



INVISIBLE SUNSCREEN

BRIGHT REVEAL™

50

BROAD SPECTRUM SPF 50

DAILY UV LOTION

Visibly reduce the appearance of dark spots*

FRAGRANCE-FREE

actual size

*diminish the look, when used as directed with other sun protection measures

1.7 FL OZ. (50ml)

Drug Facts

Active ingredients	Purpose
Avo benzene 3%	Sunscreen
Homosalate 15%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 10%	Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only
Flammable until dry. Do not use near fire, flame, or heat.
Do not use on damaged or broken skin
When using this product keep out of eyes. Rinse with water to remove.
Stop use and ask a doctor if rash occurs
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- For sunscreen use:
- shake well
 - apply liberally 15 minutes before sun exposure
 - reapply at least every 2 hours
 - use a water resistant sunscreen if swimming or sweating
 - Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - children under 6 months of age: Ask a doctor

Other information

- protect the product in this container from excessive heat and direct sun

Inactive Ingredients water, alcohol denat., glycerin, styrene / acrylates copolymer, dimethicone, butylcetyl salicylate, silica, isononyl isononanoate, isopropyl myristate, cetearyl alcohol, calcium aluminum borosilicate, tocopherol, adenosine, phenylethyl resorcinol, trisodium ethylenediamine disuccinate, ascorbyl glucoside, isocetyl stearate, ammonium acryloyldimethyltaurate / VP copolymer, caprylyl glycol, carbomer, cetearyl glucoside, inulin lauryl carbamate, lecithin, PEG-20, PEG-8 laurate, pullulan.

Drug Facts (continued)

sclerotium gum, sodium dodecylbenzenesulfonate, sodium stearyl glutamate, t-butyl alcohol, xanthan gum, phenoxyethanol

FORMULA # 88777-24
PAT: PATENTS.L'OREALPARIS.COM

FLL # V29303713

DAILY UVA/UVB PROTECTION, HELPS PREVENT AGING SIGNS*

Broad spectrum UV fluid with:

UVA/UVB FILTERS

UV filters are a first line of defense against UV induced signs of aging such as discoloration. Our UV fluid has a broad spectrum protection from both UVA (aging) and UVB (burning) rays.

ANTIOXIDANTS

Vitamin C & E help protect against environmental damage caused by free radicals that can accelerate the

appearance of aging signs.

INVISIBLE LIGHTWEIGHT TEXTURE

Lightweight & non greasy texture. Blends seamlessly with all skin tones.

*when used as directed with other sun protection measures

VISIBLE RESULTS

Immediately

Skin feels fresh & moisturized. Skin has a glowy finish.

Day after day

Skin looks brighter, tone more even. Fine lines are visibly reduced. Skin looks younger.

APPLICATION

Smooth over face & neck every morning as the last step of your skincare routine. Primes well for makeup.

BLENDS WELL WITH ALL SKIN TONES

Questions or comments?

L'ORÉAL USA, Inc., 10 Hudson Yards, New York, NY 10001 1-800-322-2036
Made in USA of US and/or imported ingredients

← ACTUAL PRODUCT SIZE →

Drug Facts	
Active Ingredient	Purpose
Zinc Oxide (21.6%)	Sunscreen
Uses	
<ul style="list-style-type: none"> Helps prevent sunburn • If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun 	
Warnings	
<p>For external use only. Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	
Directions	
<ul style="list-style-type: none"> apply generously and evenly 15 minutes before sun exposure reapply: <ul style="list-style-type: none"> after 80 minutes of swimming or sweating immediately after towel drying at least every 2 hours Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> Limit time in the sun, especially from 10 a.m.—2 p.m. Wear long-sleeved shirts, pants, hats, and sunglasses Children under 6 months of age: Ask a doctor 	
Other information	
<ul style="list-style-type: none"> Protect this product from excessive heat and direct sun • May stain some fabrics 	
Inactive Ingredients	
Water, C12-15 Alkyl Benzoate, Styrene/Acrylates Copolymer, Octyldodecyl Citrate Crosspolymer, Phenyl Trimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Dimethicone, Glycerin, Polyhydroxystearic Acid, Ethyl Methicone, Silica, Cetyl Dimethicone, Triethoxycaprylylsilane, Phenoxyethanol, Glyceryl Behenate, Sodium Chloride, Acrylates/Dimethicone Copolymer, Chlorphenesin, Phenethyl Alcohol, Avena Sativa (Oat) Kernel Flour, Caprylyl Glycol, Cetyl Dimethicone/Bis-Vinyldimethicone Crosspolymer, Tocopheryl Acetate, Chrysanthemum Parthenium (Feverfew) Flower/Leaf/Stem Juice	
Questions?	
866-428-3366; Outside US, dial collect 215-273-8755 www.aveeno.com	

AVEENO®
POSITIVELY
MINERAL™
sensitive skin
sunscreen

- lightweight formula
- non-comedogenic
- fast-absorbing
- hypoallergenic
- fragrance-free
- paraben-free
- phthalate-free
- dye-free
- dries with a matte finish
- TSA travel-friendly size

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CONSUMER INC.**
Skillman, NJ 08558
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DERMATOLOGIST
RECOMMENDED

Aveeno®

**POSITIVELY
MINERAL™**
sensitive skin
sunscreen

BROAD SPECTRUM SPF 50
FOR FACE

naturally-sourced
100% zinc oxide
active ingredient

sweat + water resistant
(80 min)

SPF
50

2.0 fl. oz (59 mL)

Heading outside?

AVEENO® has got your skin covered so that you can enjoy the sun everyday.

AVEENO® POSITIVELY MINERAL™ Lotion with Broad Spectrum SPF 50 For Face contains 100% zinc oxide active ingredient and goes beyond UVA/UVB protection.

This oil-free mineral sunscreen is gentle to eyes and skin and layers invisibly under makeup.



예시 4

SHISEIDO



BENEFIANCE
NutriPerfect

Day Cream
BROAD SPECTRUM
SPF 18

SUNSCREEN
PRO-FORTIFYING
Carnosine DP™

50mL NET WT. 1.8 OZ.

Drug Facts (continued)

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients

WATER • BUTYLENE GLYCOL • GLYCERIN • DIPROPYLENE GLYCOL • DIMETHICONE • GLYCERYL STEARATE SE • BEHENYL ALCOHOL • PEG/PPG-14/7 DIMETHYL ETHER • POLYBUTYLENE GLYCOL/PPG-5/1 COPOLYMER • HYDROGENATED POLYDECENE • ISOPROPYL MYRISTATE • MYRISTYL MYRISTATE • MICROCRYSTALLINE WAX • PEG-40 STEARATE • SILICA • CARBOSINE • XANTHAN GUM • BRYLITROL • TOCOPHERYL ACETATE • POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE • PHANTHERYL ETHER • SODIUM ACETYLATED HYALURONATE • SCORBITAN TRISTEARATE • STEARYL ALCOHOL • CELLULOSE GUM • SODIUM METAPHOSPHATE • TRISODIUM EDTA • BHT • SODIUM METABISULFITE • TOCOPHEROL • PHENOXYETHANOL • FRAGRANCE • IRON OXIDES ▼

GLUE AREA
NO INK & COATING

SHISEIDO
BENEFIANCE
NUTRIPERFECT
DAY CREAM
BROAD SPECTRUM SPF 18

Give strength to skin affected by hormonal changes.

A powerful protective day cream created especially for mature skin experiencing wrinkles, discolorations, and loss of resilience associated with the hormonal changes due to aging. Defends against dryness, pollution, and the harmful effects of UV rays. Restores skin density and firmness for younger-looking facial contours.

- Smooth over face each morning after cleansing and balancing skin.
- Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.

DERMATOLOGIST-TESTED.

<http://s1872.com/19110AA>
See our website for more information.

Specially formulated by
Shiseido Laboratories, Japan.

SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10022
MADE IN U.S.A.
GLO. 1910
www.shiseido.com



Drug Facts (continued)

Other Information

- protect this product in this container from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-800-906-7503

7 30852 19110 5

19110-44-5040

Drug Facts

Active ingredients

AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 2.0%	Sunscreen

Purpose

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

SHISEIDO
GINZA TOKYO

東京銀座

REVITALESSENCE
SKIN GLOW
Foundation

BROAD SPECTRUM
SPF30

Sunscreen

Bio-BoostRED Technology

Fermented Kefir+
Niacinamide

30mL 1FL. OZ.

Drug Facts (continued)

Inactive ingredients

WATER • DIPHENYLSILOXY PHENYL TRIMETHICONE • DIPROPYLENE GLYCOL • GLYCERIN • NIACINAMIDE • ALCOHOL DENAT. • PEG-8 • PEG-60 HYDROGENATED CASTOR OIL • LACTOBACILLUS FERMENT • AMMONIUM ACRYLOYLDIMETHYLTAURATE/BEHENETH-25 METHACRYLATE CROSSPOLYMER • TOCOPHERYL ACETATE • SODIUM DILAURAMIDOGUTAMIDE LYSINE • MAGNESIUM CHLORIDE • POLYQUATERNIUM-51 • LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL • SANGUISORBA OFFICINALIS ROOT EXTRACT • CAMELLIA SINENSIS LEAF EXTRACT • HYDROGENATED POLYISOBUTENE • PEG-12 DIMETHICONE • ISOSTEARIC ACID • POLYGLYCERYL-6 POLYRICINOLEATE • PEG-100 HYDROGENATED CASTOR OIL • BUTYLENE GLYCOL • ALUMINUM HYDROXIDE • DIMETHYLACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE CROSSPOLYMER • ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER • TRISODIUM EDTA • BHT • TOCOPHEROL • POTASSIUM HYDROXIDE • ALCOHOL • SODIUM METABISULFITE • PEG/PPG-19/19 DIMETHICONE • STEARIC ACID • PHENOXYETHANOL • TITANIUM DIOXIDE • IRON OXIDES

Other Information

■ protect this product in this container from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-800-906-7503

<M111458-811>



<http://s1872.com/19342AA>

See our website for more information.



30% Recycled glass for bottle

FSCマーク
W26.25×H12

SHISEIDO
REVITALESSENCE
SKIN GLOW
FOUNDATION

A skincare-active foundation that provides a healthy glowing finish and **24-hour hydration***1. In just 1 week*2, bare skin is visibly more even-toned, hydrated and smooth. Powered by **Fermented Kefir+** and **Niacinamide**, this foundation packs the same level of effective skincare ingredients as a SHISEIDO serum. Medium coverage. **12-hour wear***3.

*1 *3 Clinically tested on 27/31 women.

*2 Consumer tested on 109 women.

Drug Facts

Active ingredient Purpose

OCTINOXATE 6.9% ... Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

SHISEIDO AMERICAS
CORPORATION DIST.
NEW YORK, NY 10017
MADE IN U.S.A.

www.shiseido.com



Drug Facts (continued)

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

● Shake well before use.

FRAGRANCE FREE.

SUITABLE FOR ALL SKIN TYPES
INCLUDING SENSITIVE SKIN.

DERMATOLOGIST-TESTED.
NON-NONCOMEDOGENIC.



Power of Science.
#ALIVEwithBeauty

Drug Facts

Active ingredients

Avobenzone 3%
Homosalate 10%
Octisalate 5%
Octocrylene 5%

Purpose
Sunscreen

Use helps prevent sunburn

Warnings

For external use only

Do not use on damaged or broken skin

When using this product, keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions For sunscreen use:

- apply generously and evenly 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- children under 6 months of age: Ask a doctor
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses

Other information protect the product in this container from excessive heat and direct sun

Inactive ingredients Water, Alcohol Denat., Lauryl Methacrylate/Sodium Methacrylate Crosspolymer, Diethylhexyl 2,6-Naphthalate, Glycerin, Dextrin Palmitate, Dicaprylyl Ether, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Glyceryl Behenate, Phenyl Trimethicone, Cetyl Alcohol, Sorbitan Distearate, Sodium Hydroxide, Stearoyl Glutamic Acid, Arginine, Disodium EDTA, Sodium Hyaluronate, Phenoxyethanol, Citral, Geraniol, Limonene, Linalool.

Questions or comments? 1-800-BIORE-11



Questions? 1-888-BIORE-11
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protected by any US patents.
28295-0-600

WHAT IT DOES:

This innovative daily UV Moisturizer is the future of sun protection for the future of your skin. This unique formula is developed from Bioré Japan's water-based sunscreens, widely loved for their fresh textures and invisible, clean protection. This feather-light UV moisturizer, with a light citrus scent and Broad Spectrum SPF 50 to help protect from UV rays and UV damage, spreads easily and absorbs instantly for a sheer finish on all skin tones with no white cast.

- Hyaluronic Acid

PROTECT YOUR PORES!

Bioré

UV AQUA RICH

WEIGHTLESS MOISTURIZER



BROAD
SPECTRUM
SPF 50
SUNSCREEN

Aqua
Rich

1.7 FL OZ (50 mL)

OUR COMMITMENT: TAKING CARE OF PORES & THE PLANET

We're committed to making products that are ethically and sustainably responsible.

- Our products are formulated for performance and safety in mind using only high-quality ingredients and rigorous safety standards.
- We are proud to be a carbon neutral brand – offsetting the carbon footprint of our products and supporting climate initiatives.



climatepartner.com/
14090-2710-1001
*Product CO₂ compensated



how2recycle.info

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