

DOCUMENT NO.: 20200406-E10

ATTN: SISKINKOREA CO.,LTD.

60, Buil-ro 809beon-gil, Bucheon-si, Gyeonggi-do 14665, Korea, South (KOR)

DATE: April 06, 2020

Title: SISKINKOREA CO.,LTD. U.S. FDA OTC(Over-the-counter) Drugs registration

To export OTC products to the U.S., the manufacturer must register its establishment and product to the U.S. FDA under 21 CFR Part 201.

The SISKINKOREA CO.,LTD. manufacturing facility registration request has been completed.

- DUNS #: 695625974

NDC labeler code request has been assigned.

- NDC Labeler code of SISKINKOREA CO.,LTD. : 74514

Up to now, registration for 8 OTC products produced by SISKINKOREA CO., LTD. has been completed as Attachment 1.

Registered product name	NDC Code(National Drug Code)	Package Description
OH MY CLEAN PREMIUM SANITIZER Gel	74514-0057-1	50 mL in 1 BOTTLE, PUMP (74514-0057-1)
OH MY CLEAN PREMIUM SANITIZER Gel	74514-0170-1	100 mL in 1 BOTTLE, PUMP (74514-0170-1)
OH MY CLEAN PREMIUM SANITIZER Gel	74514-0570-1	500 mL in 1 BOTTLE, PUMP (74514-0570-1)
OH MY CLEAN PREMIUM SANITIZER MIST	74514-9570-1	500 mL in 1 BOTTLE, SPRAY (74514-9570-1)
OH MY CLEAN THE PURE SANITIZER Gel	74514-0056-1	50 mL in 1 BOTTLE, PUMP (74514-0056-1)
OH MY CLEAN THE PURE SANITIZER Gel	74514-0162-1	100 mL in 1 BOTTLE, PUMP (74514-0162-1)
OH MY CLEAN THE PURE SANITIZER Gel	74514-0562-1	500 mL in 1 BOTTLE, PUMP (74514-0562-1)
OH MY CLEAN THE PURE SANITIZER MIST	74514-9562-1	500 mL in 1 BOTTLE, SPRAY (74514-9562-1)

Attachment 1. How to verify product registration?

COMVALIS CORP.

Representative Director

SEOUNG HOON BAEK 

Attachment 1. How to verify product registration?

[Product listing verification]

Access FDA link : https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm

Select **NDC Code** -> Type **74514** -> Click **Search or Enter**

OR

Select **Labeler** -> Type **SISKINKOREA** -> Click **Search or Enter**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
OH MY CLEAN PREMIUM SANITIZER Gel	74514-0057-1	35 mL/50mL	GEL	TOPICAL	part333A	SISKINKOREA CO.,LTD.	74514-0057	ALCOHOL	ALCOHOL	HUMAN OTC DRUG	04/01/2020	N/A	OTC MONOGRAPH NOT FINAL	50 mL in 1 BOTTLE, PUMP (74514-0057-1)	N/A	N/A
OH MY CLEAN PREMIUM SANITIZER Gel	74514-0170-1	70 mL/100mL	GEL	TOPICAL	part333A	SISKINKOREA CO.,LTD.	74514-0170	ALCOHOL	ALCOHOL	HUMAN OTC DRUG	04/01/2020	N/A	OTC MONOGRAPH NOT FINAL	100 mL in 1 BOTTLE, PUMP (74514-0170-1)	N/A	N/A
OH MY CLEAN PREMIUM SANITIZER Gel	74514-0570-1	350 mL/500mL	GEL	TOPICAL	part333A	SISKINKOREA CO.,LTD.	74514-0570	ALCOHOL	ALCOHOL	HUMAN OTC DRUG	04/01/2020	N/A	OTC MONOGRAPH NOT FINAL	500 mL in 1 BOTTLE, PUMP (74514-0570-1)	N/A	N/A
OH MY CLEAN PREMIUM SANITIZER MIST	74514-9570-1	350 mL/500mL	LIQUID	TOPICAL	part333A	SISKINKOREA CO.,LTD.	74514-9570	ALCOHOL	ALCOHOL	HUMAN OTC DRUG	04/01/2020	N/A	OTC MONOGRAPH NOT FINAL	500 mL in 1 BOTTLE, SPRAY (74514-9570-1)	N/A	N/A
OH MY CLEAN THE PURE SANITIZER Gel	74514-0056-1	31 mL/50mL	GEL	TOPICAL	part333A	SISKINKOREA CO.,LTD.	74514-0056	ALCOHOL	ALCOHOL	HUMAN OTC DRUG	04/01/2020	N/A	OTC MONOGRAPH NOT FINAL	50 mL in 1 BOTTLE, PUMP (74514-0056-1)	N/A	N/A
OH MY CLEAN THE PURE SANITIZER Gel	74514-0162-1	62 mL/100mL	GEL	TOPICAL	part333A	SISKINKOREA CO.,LTD.	74514-0162	ALCOHOL	ALCOHOL	HUMAN OTC DRUG	04/01/2020	N/A	OTC MONOGRAPH NOT FINAL	100 mL in 1 BOTTLE, PUMP (74514-0162-1)	N/A	N/A
OH MY CLEAN THE PURE SANITIZER Gel	74514-0562-1	310 mL/500mL	GEL	TOPICAL	part333A	SISKINKOREA CO.,LTD.	74514-0562	ALCOHOL	ALCOHOL	HUMAN OTC DRUG	04/01/2020	N/A	OTC MONOGRAPH NOT FINAL	500 mL in 1 BOTTLE, PUMP (74514-0562-1)	N/A	N/A
OH MY CLEAN THE PURE SANITIZER MIST	74514-9562-1	310 mL/500mL	LIQUID	TOPICAL	part333A	SISKINKOREA CO.,LTD.	74514-9562	ALCOHOL	ALCOHOL	HUMAN OTC DRUG	04/01/2020	N/A	OTC MONOGRAPH NOT FINAL	500 mL in 1 BOTTLE, SPRAY (74514-9562-1)	N/A	N/A

[Drug Establishment Registration verification]

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

Type **SISKINKOREA** -> Click **Search or Enter**

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Search Results for SISKINKOREA

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
SISKINKOREA CO.,LTD.		695625974	LABEL; MANUFACTURE; REPACK;	60, Bul-ro 809beon-gil, Bucheon-si, Gyeonggi-do 14665, Korea, South (KOR)	12/31/2020

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