# CASE #1 – Hand Sanitizer Wipes

Email Sent Date: 08-OCT-2020

To: aboss@wonderpharma.com

Subject: FDA Hand Sanitizer Listing Deficiency Letter – Wonder Pharma -- Action Required

Body:
FDA Hand Sanitizer Listing Deficiency Letter – Wonder Pharma -- Action Required

08-OCT-2020

A. Boss
Wonder Pharma
123 Main Street
Anywhere, USA

Dear A. Boss,

This letter is to notify you that we have identified an apparent problem with your firm's alcohol-based hand sanitizer listing submission to the Food and Drug Administration (FDA). The specific National Drug Code(s) (NDC) and associated error(s) or omission(s) that we identified are itemized at the end of this letter. As explained below, if the submitted data are inaccurate or incomplete, that can have adverse results for public health and may constitute a violation of the law. Therefore, please examine the listing information for the drug(s) included in the table below, and within 14 days of receipt of this letter, ensure that you have provided complete and accurate listing information. Within that time period, please notify us at edrls@fda.hhs.gov that you have made corrections, or if you believe that your listing submission is accurate and complete without revision, please provide your reasoning and any supporting information for our consideration.

New listing information or updates to existing listing files should be submitted via Structured Product Labeling (SPL) using the FDA's electronic Drug Registration and Listing System (DRLS). To make correction(s), you should access the existing listing file(s) using the same SetID, make any necessary changes and submit the corrected listing. See DRLS instructions for more information.

The eDRLS Helpdesk can assist with errors encountered during the submissions process. Please contact edrls@fda.hhs.gov if the submission of the revised SPL results in a validation error and include a list of all validation errors and the Core-ID of the failed submission.

The accuracy and completeness of your listing submission is important to ensure compliance with the law and to support the public health. Every person required to register with the FDA must, at the time of initial registration, list all drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution. (See Section 510(j)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 360(j)(1); see also 21 CFR 207.17 and 207.41). Drug listing information must be updated in June and December each year. These updates must include any drugs not previously listed, any

previously listed drug no longer manufactured or distributed, and certain changes to information for previously listed drugs. (See Section 510(j)(2) of the FD&C Act, 21 U.S.C. 360(j)(2), see also 21 CFR 207.57.) Failure to properly list a drug product as required by Section 510(j) of the FD&C Act is prohibited and will render a drug misbranded, which in turn will make its distribution in interstate commerce a violation of Federal law. (See Sections 301(a) & (p), 502(o) of the FD&C Act, 21 U.S.C. 331(a) & (p), 352(o)).

We note that FDA published a guidance document to communicate its temporary policy for the preparation of certain alcohol-based hand sanitizer products during the COVID-19 pandemic. If certain circumstances are present, FDA does not intend to take action against firms that prepare alcohol-based hand sanitizers for the duration of the COVID-19 pandemic for certain violations of the FD&C Act. One of these circumstances is that firms register their facility(ies) and list their hand sanitizer products in the FDA Drug Registration and Listing System (DRLS, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/drug-registration-and-listing-system-drls-and-edrls).

Accurate and complete drug registration and listing information is important to the public health. FDA relies on this information to help manage drug shortages, monitor safety issues that may arise with product distributed to the public, and manage product recalls, among other important public health activities. The data included in your drug listing submission is also published in FDA's NDC Directory and the National Library of Medicine's DailyMed site—two public databases that are consulted by stakeholders including consumers, health care providers, and payors who are seeking information about drug products in the marketplace. To help ensure the accuracy of information available to the public, if we do not hear back from you or a corrected listing submission is not made within 14 days of the receipt of this letter, FDA may temporarily block the product listing from publication in the NDC Directory and DailyMed websites until this matter is resolved.

As noted above, please contact edrls@fda.hhs.gov if you have any questions.

Sincerely,

Electronic Drug Registration and Listing Staff (jac)
FDA/CDER/Office of Compliance
edrls@fda.hhs.gov

| NDC | Proprietary Name | Issue |
|---|---|---|
| 55555-555 | Wonderdrug Hand Sanitizer Wipes | wrong active ingredients and strengths |

## CONTENT OF LABELING

**Active Ingredient [ OTC - ACTIVE INGREDIENT SECTION ]**

Alcohol 80% V/V

**Purpose [ OTC - PURPOSE SECTION ]**

Antimicrobial

**Uses [ INDICATIONS & USAGE SECTION ]**

- for hand sanitizing to decrease bacteria on skin when water and soap are not available.
- recommended for repeated use.

**Warnings [ WARNINGS SECTION ]**

**For external use only. Flammable: keep away from fire or flame. When using this product** do not use in or near eyes. If contact occurs, flush thoroughly with water. **Stop use and contact a doctor** if irritation or redness pers

**Keep out of reach of children [ OTC - KEEP OUT OF REACH OF CHILDREN SECTION ]**

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

**Directions [ DOSAGE & ADMINISTRATION SECTION ]**

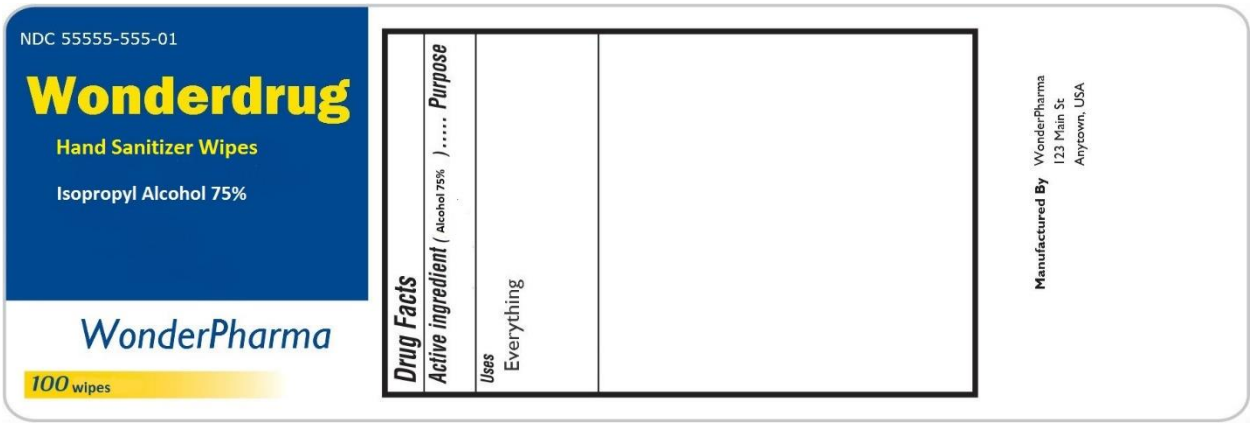
- remove wipe
- wet hands thoroughly with wipe and allow hands to dry without wiping

**Inactive ingredients [ INACTIVE INGREDIENT SECTION ]**

Water, Glycerin, Hydrogen Peroxide

**Questions, Comments? [ OTC - QUESTIONS SECTION ]**

- Customer.questions@wonderpharma.com
- (555) 555-5555



## PRODUCT DATA ELEMENTS

NDC Product Code: * 55555-555

Proprietary Name: * Wonder Pharma Hand Sanitizer W

Suffix:

Non Proprietary Name: * Hand Sanitizer Wipes

DEA Schedule: -Select DEA Schedule-

Dosage Form: * CLOTH

Route of Administration: *

AURICULAR (OTIC)
BUCCAL
CONJUNCTIVAL
CUTANEOUS
DENTAL
ELECTRO-OSMOSIS

TOPICAL

Source NDC:

## MARKETING DETAILS

Marketing Status: * ACTIVE

Marketing Start Date: * 05-01-2020

Marketing Category: * OTC MONOGRAPH NOT FINAL

Application Number/ Regulatory Citation: part333A

## INGREDIENTS

ADD INGREDIENT

row(s) 1 - 4 of 4

| | SUBSTANCE NAME | UNII / NDC | STRENGTH | TYPE |
|---|---|---|---|---|
| | ALCOHOL | 3K9958V90M | 80 mL | ACTIB |
| | GLYCERIN | PDC6A3C0OX | | IACT |
| | HYDROGEN PEROXIDE | BBX060AN9V | | IACT |
| | WATER | 059QF0KO0R | | IACT |

## PRODUCT IMAGE (FOR SOLID ORAL DOSAGE FORMS ONLY)

UPLOAD IMAGE

**Note:** JPG files only. Package images and other labeling should be uploaded under the Content of Labeling tab.

Select a File: Browse...

## CHARACTERISTICS

ADD CHARACTERISTIC

row(s) 1 - 2 of 2

| | CHARACTERISTIC | VALUE | ADDITIONAL DESCRIPTION |
|---|---|---|---|
| | SPLCOLOR | WHITE | - |
| | SPLSHAPE | RECTANGLE | - |

## PACKAGING

ADD PACKAGE

row(s) 1 - 1 of 1

| | PACKAGE NDC | NO OF LEVELS | PACKAGE TYPE | QUANTITY | UNIT OF MEASURE | MARKETING STATUS | MARKETING START DATE | MARKETING END DATE | CLONE |
|---|---|---|---|---|---|---|---|---|---|
| | 55555-555-01 | 2 | CANISTER | 100 | 1 | ACTIVE | 02-01-2018 | - | |

## PACKAGING

### INNERMOST LEVEL

| | |
|---|---|
| Check for Deletion | ☐ |
| Package NDC: | |
| Package Type: * | CANISTER |
| Quantity: * | 200 |
| Unit of Measure: * | mL |
| Combination Product Type: | Type 0: Not a Combination Product |
| Marketing Status: | - Select Value - |
| Marketing Start Date: | |
| Marketing End Date: | |

### OUTERMOST LEVEL

| | |
|---|---|
| Check for Deletion | ☐ |
| Is this a sample package ? | ☐ |
| Package NDC: | 55555-555-01 |
| Package Type: * | CANISTER |
| Quantity: * | 100 |
| Unit of Measure: * | 1 |
| Combination Product Type: | - Select Value - |
| Marketing Status: | active |
| Marketing Start Date: | 05-01-2020 |

# CASE #2 – Inactivated drugs

Email Sent Date: 05-JUN-2020

To: aboss@wonderpharma.com

Subject: FDA Hand Sanitizer Listing Deficiency Letter – Wonder Pharma -- Action Required

Body:
FDA Hand Sanitizer Listing Deficiency Letter – Wonder Pharma -- Action Required

05-JUN-2020

A. Boss
Wonder Pharma
123 Main Street
Anywhere, USA

Dear A. Boss,

You are receiving this email because you are identified as the point of contact for one or more active drug listing record(s) that is in jeopardy of being inactivated due to a reference to at least one manufacturing establishment not duly registered with FDA. This can occur if the establishment deregisters or fails to renew its registration after the product listing has been updated or certified. The inactivation is planned to occur in mid-July 2020.

A list of your candidate NDCs linked to at least one establishment not duly registered is provided in the table below. To prevent inactivation of the product listing:

1. Review the status for all establishment data in the drug listing file for identified listing(s) below. Registration status for any establishment may be verified at the FDA's Drug Establishment Current Registration Site.
2. For each drug listing file:
    a. *If the list of establishments needs to be updated*, submit an updated drug listing file for that NDC identifying a new manufacturing establishment that is currently registered, or
    b. *If the list of establishments is accurate but one or more failed to renew its annual registration*, submit an updated establishment registration for the existing establishment (or contact the establishment and notify them of the need to re-register.)
    c. If the listed product is being discontinued, submit an updated drug listing file with "COMPLETE" as the marketing status and a Marketing End Date equal to the last lot expiry date (may be in the future).

A successful submission from either Step 2a or 2b will immediately prevent the listing from being inactivated. A successful submission from Step 2c will discontinue the drug, will remove it from public sites on its Marketing End Date, and prevents the listing data from being inactivated.

**Notice for manufacturers of COVID-19 related drugs**: If you believe any of your products identified below are used in COVID-19 related treatment **and** you are not able to complete Steps 2a, 2b, or 2c before mid-July 2020, you may contact FDA's drug registration and listing staff at the email address below and request an extension.

| Product NDC(s) | Proprietary Name(s) | Spl Set ID |
|---|---|---|
| 55555-555 | Wonder Pharma Hand Sanitizer | b005d2f3-e2f1-f236-e053-2a95af0a776b |

Please visit www.fda.gov/edrls or contact edrls@fda.hhs.gov with questions about updating your drug listing records.

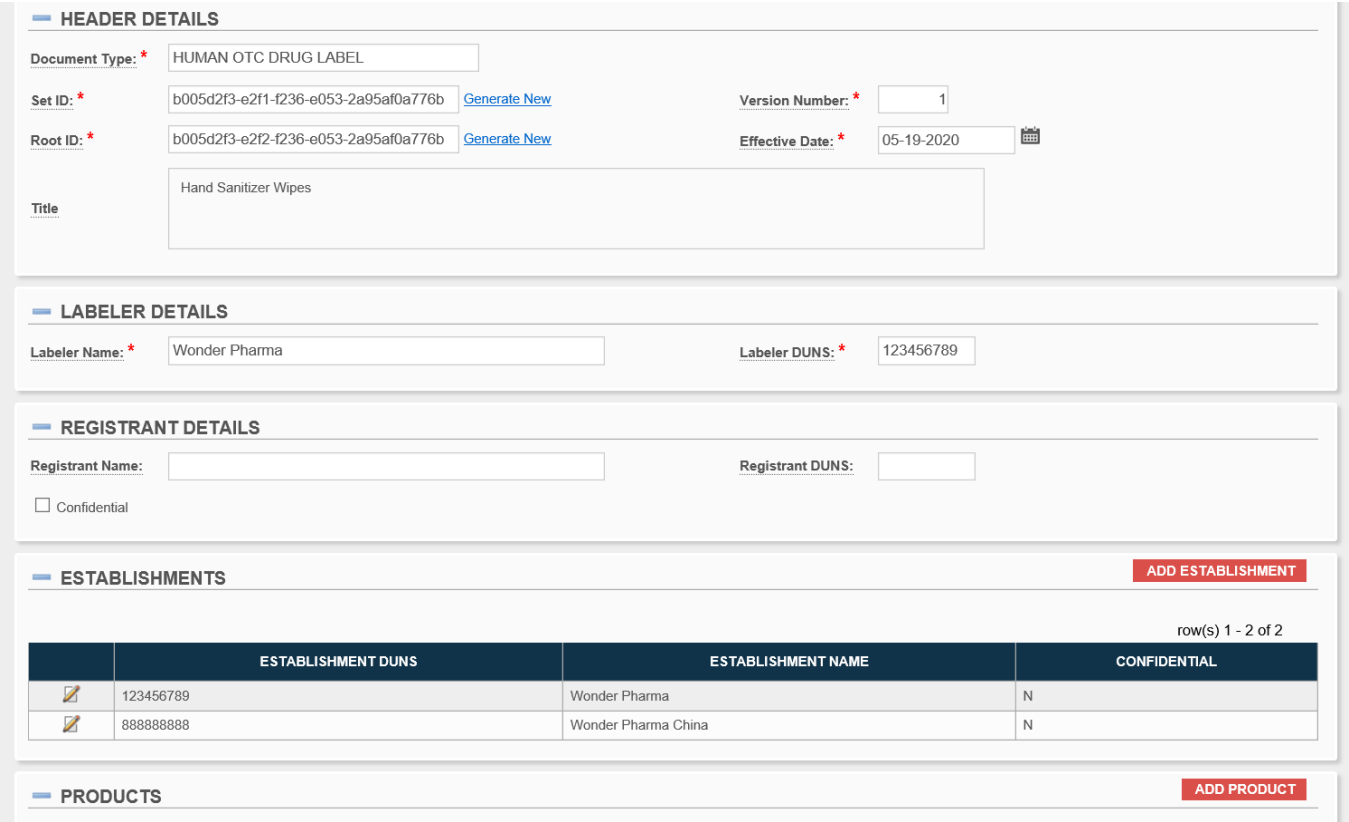
Inactivation of drug listing data by FDA is not a mechanism that replaces a firm's responsibility to discontinue a listed drug. If manufacturing or distribution of the listed drug is discontinued in the U.S., your drug listing file should be updated in June to reflect this change under 21 CFR 207.57(b)(ii).

Sincerely,

Paul Loebach, Director

Drug Registration and Listing Staff
FDA/CDER/Office of Compliance/Office of Program and Regulatory Operations

# DRUG LISTING SPL



HEADER DETAILS

Document Type: * HUMAN OTC DRUG LABEL

Set ID: * b005d2f3-e2f1-f236-e053-2a95af0a776b Generate New

Version Number: * 1

Root ID: * b005d2f3-e2f2-f236-e053-2a95af0a776b Generate New

Effective Date: * 05-19-2020

Title: Hand Sanitizer Wipes

LABELER DETAILS

Labeler Name: * Wonder Pharma

Labeler DUNS: * 123456789

REGISTRANT DETAILS

Registrant Name:

Registrant DUNS:

Confidential

ESTABLISHMENTS

ADD ESTABLISHMENT

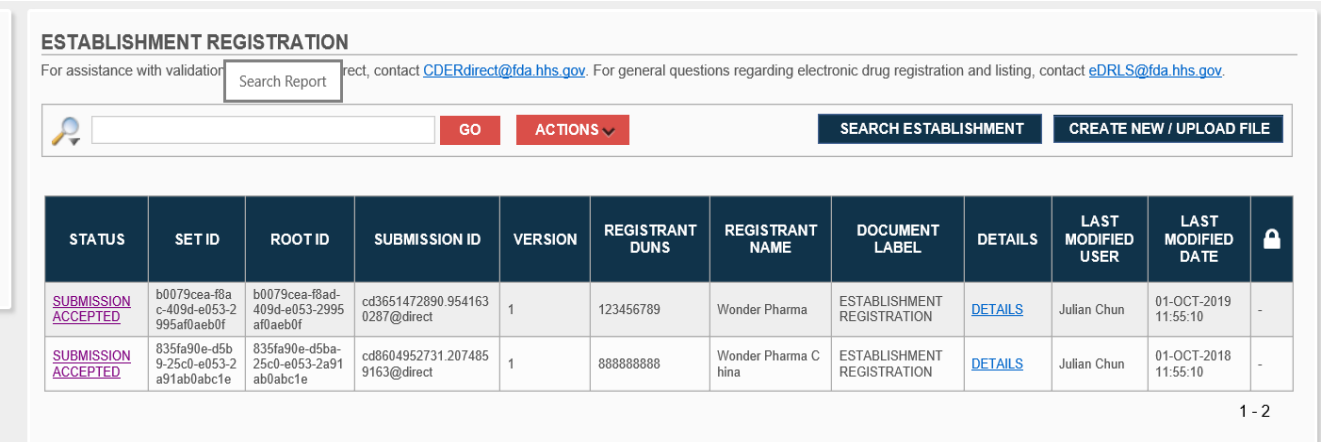
row(s) 1 - 2 of 2

| | ESTABLISHMENT DUNS | ESTABLISHMENT NAME | CONFIDENTIAL |
|---|---|---|---|
| | 123456789 | Wonder Pharma | N |
| | 888888888 | Wonder Pharma China | N |

PRODUCTS

ADD PRODUCT

# ESTABLISHMENT REGISTRATION



ESTABLISHMENT REGISTRATION

For assistance with validation Search Report rect, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic drug registration and listing, contact eDRLS@fda.hhs.gov.

GO ACTIONS SEARCH ESTABLISHMENT CREATE NEW / UPLOAD FILE

| STATUS | SET ID | ROOT ID | SUBMISSION ID | VERSION | REGISTRANT DUNS | REGISTRANT NAME | DOCUMENT LABEL | DETAILS | LAST MODIFIED USER | LAST MODIFIED DATE | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| SUBMISSION ACCEPTED | b0079cea-f8ac-409d-e053-2995af0aeb0f | b0079cea-f8ad-409d-e053-2995af0aeb0f | cd3651472890.9541630287@direct | 1 | 123456789 | Wonder Pharma | ESTABLISHMENT REGISTRATION | DETAILS | Julian Chun | 01-OCT-2019 11:55:10 | - |
| SUBMISSION ACCEPTED | 835fa90e-d5b9-25c0-e053-2a91ab0abc1e | 835fa90e-d5ba-25c0-e053-2a91ab0abc1e | cd8604952731.2074859163@direct | 1 | 888888888 | Wonder Pharma China | ESTABLISHMENT REGISTRATION | DETAILS | Julian Chun | 01-OCT-2018 11:55:10 | - |

1 - 2

## HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION

Set ID: * b0079cea-f8ac-409d-e053-2995af0aeb0f

Root ID: * b0079cea-f8ad-409d-e053-2995af0aeb0f

Version Number: * 1

Effective Date: * 01-01-2020

## REGISTRANT DETAILS

Registrant Name: * Wonder Pharma

Registrant DUNS: * 123456789

### REGISTRANT CONTACT DETAILS

Contact Name: * A. Boss

Contact Email: * aboss@wonderpharma.com

Contact Phone: * 1-555-555-5555

Phone Extension:

### REGISTRANT CONTACT ADDRESS

Country: * United States

Street Address: * 123 Main Street

City: * Anytown

State: * Maryland

Postal Code: * 11111

## ESTABLISHMENTS

row(s) 1 - 1 of 1

| | ESTABLISHMENT DUNS | ESTABLISHMENT FEI | ESTABLISHMENT NAME |
|---|---|---|---|
| | 123456789 | - | Wonder Pharma |

## HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION

Set ID: * 835fa90e-d5b9-25c0-e053-2a91ab0abc1e

Root ID: * 835fa90e-d5ba-25c0-e053-2a91ab0abc1e

Version Number: * 1

Effective Date: * 05-01-2020

## REGISTRANT DETAILS

Registrant Name: * Wonder Pharma China

Registrant DUNS: * 888888888

### REGISTRANT CONTACT DETAILS

Contact Name: * Mulan Princess

Contact Email: * mulan@wonderpharma.com

Contact Phone: * 86-888-8888-8888

Phone Extension:

### REGISTRANT CONTACT ADDRESS

Country: * China

Street Address: * 123 Main Street

City: * Anywhere

State/Province:

Postal Code: * 88888

## ESTABLISHMENTS

row(s) 1 - 1 of 1

| | ESTABLISHMENT DUNS | ESTABLISHMENT FEI | ESTABLISHMENT NAME |
|---|---|---|---|
| | 888888888 | - | Wonder Pharma China |