



Standard Operating Procedure

TITLE: Final Pharmaceutical Product Recall

SOP: QA-211

Revision 006, 10/7/25

Page 1 of 6

1. PURPOSE

To establish a procedure for the timely, voluntary, efficient, and compliant recall of finished pharmaceutical product from all customers.

2. SCOPE

Applies to all finished pharmaceutical products that have been manufactured, repackaged, or shipped from the facility.

3. RESPONSIBILITY

Quality Assurance Department

4. ASSOCIATED MATERIALS

FDA *Guidance for Industry, "Products Recalls, Including Removals and Corrections"*, 11/3/03

21 CFR 10.115 FDA's Good Guidance Practices

Quality Assurance Department

4. PROCEDURE

NOTE: Substitutions and exchanges of materials without customer complaints are not classified as recalled products. However, they still need to follow all the requirements stated in NTC-050 Returns Good Policy.

5.1 If a recall of a finished pharmaceutical product is determined to be necessary, the Quality Director consults with the management and consultants of the company and determines the extent and nature of the recall. The FDA is informed, both by telephone and in written form, of all the necessary details, as appropriate to the situation.

5.2 The Quality Director collects the following information:

5.2.1 all batch records including production records, laboratory records, packaging records, labeling records, and distribution records in question; and

5.2.2 retain samples of all batch/lot numbers in question.



Standard Operating Procedure

TITLE: Final Pharmaceutical Product Recall

SOP: QA-211

Revision 006, 10/7/25

Page 2 of 6

5.3 **Recall Submission Process/ Notifications to Customers/Importers**

After the decision is made that the recall is appropriate, notify local FDA district Recall Coordinator as soon as possible. This need to be done prior to the issuance of press or written notification to customer.

After the decision is made that the recall is appropriate, notify local FDA district Recall Coordinator as soon as possible. This need to be done prior to the issuance of press or written notification to customer and international importers.

Immediately after FDA notification is sent out, Solesence, Inc. will immediately send out an email to all affected customers and international importers as determined by the distribution records of a particular lot kept in ERP system. Notification will include the nature of recall with product name with associated lot number(s) date of distribution.

For a Canadian importer and/or customer holding a valid site license will be inform within 24 hours after a recall decision is made via an email and followed with a phone call to assure that the information is received and acknowledged in a timely manner. The importer in Canada is responsible for initiation, notification, and reporting of recall in Canada to HPFBI Regional Operational Centre.

The following listed information must be submitted to FDA;

Product Information:

- Product name,
- batch number(s),
- description of products (solid, liquid, etc.)
- type of packaging
- intended use or application, and
- shelf life (if applicable)
- two complete set of all labeling and inserts
- NDA/ANDA numbers (if applicable)
- NDC number
- category (such as OTC or prescription)
- strength
- route of administration (such as topical, oral, etc.)



Standard Operating Procedure

TITLE: Final Pharmaceutical Product Recall

SOP: QA-211

Revision 006, 10/7/25

Page 3 of 6

Recall Firm Information

- Firm name and address
- FDA registration number (if applicable)
- Identify firm type (Soleseance, Inc. is considered a Manufacturer)

Contact (Recalling Firm)

- Name/Title/Position/Fax Number/E-mail Address for RECALL contact
- Name/Title/Position/Fax Number/E-mail Address for most responsible person
- Name/Title/Position/Fax Number/E-mail Address for public contact

Reason for RECALL

- Explain defective and or violative description
- Explanation of elements affecting safety and performance
- If the recall is due to the presence of foreign materials, describe nature
- If the recall is due to the presence of contamination, describe nature
- If the recall is due to failure of specification, describe nature
- If the recall is due to label/ingredient issue describe nature
- Explain how the problem occurred and dates occurred
- Explain how the problem was discovered and dates discovered
- Explain if problem has affected all units subject to RECALL or just a portion of units in a lot(s) subject to RECALL and explain why.
- Provide detailed information related to any associated compliant(s)
- If a state agency is involved identify name and contact information



Standard Operating Procedure

TITLE: Final Pharmaceutical Product Recall

SOP: QA-211

Revision 006, 10/7/25

Page 4 of 6

Health Hazard Assessment

- Provide assessment of health risk associated with the deficiency (NOTE: this does not apply if recall is due to misbranded issues and defects with no health issues)

Depth of Recall/Notifications

- The recall notification should clearly identify the depth to which the recall is extended (e.g., wholesale, retail or user level)
- If the product could have been further distributed by firm's customers, then firm must include instruction to subrecall. Subrecall instruction should also include the depth of the recall, e.g., "If you have further distributed this product, you should notify your customer to the retail level"
- Notification to customer including Canadian Importers must include instruction such as;
 - Remove from Sale
 - Cease Distribution
 - Subrecall (if apply)
 - Return Product
 - Explain procedure for product correction
 - Include a RETURN RESPONSE letter or form. This letter/form must include all instruction from the RECALL letter. Firm's customer(s) are required to indicate that they followed every instruction.
 - All customer, including international importers in the distribution chain must be notified of the RECALL. This include any foreign importers and upstream customers, for example, a Canadian importer holding a valid site license must be inform within 24 hours after a recall decision is made.
- The Recall Letter is mailed to all concerned parties and is mailed in envelopes marked with "URGENT DRUG RECALL" in bold red letters. The Recall Letters are sent by certified mail and return receipt required.
- All customer, including international importers in the distribution chain are notified of the RECALL.



Standard Operating Procedure

TITLE: Final Pharmaceutical Product Recall

SOP: QA-211

Revision 006, 10/7/25

Page 5 of 6

5.5 Public Notification

In a situation where the product may pose a significant health hazard and recalled product is in the hands of consumers, a press release is usually appropriate. Issuance of a press release should be the highest priority and it should be issued promptly. Joint press release may benefit the firm and FDA by alerting the public to a serious health hazard or situation deemed to be in public interest.

To assure the broadest coverage, press release should be issues through the Associated Press (AP)

5.6 Effectiveness of the Recall

Effectiveness of the recall must be evaluated and documented through an effectiveness check process. The purpose of an effectiveness check is to verify firm's recall notification letter was received by the customer, that the customer read and understood the letter and followed the recall instructions. The purpose also verifies that recall reached the appropriate level in the distribution chain. If the effectiveness check indicates the recall information was not received or followed, then a corrective action must be initiated to make the recall effective.

5.7 Recall Status Report

A recall status report must be submitted to local District Recall Coordinator at least on a monthly basis (sooner if required) The report should include;

- number of customers notified
- number of customers responded
- quantity of RECALLED product returned or accounted for
- detail of RECALL Effectiveness check

5.8 Corrective and Preventive Actions

Corrective actions along with root cause and preventive actions of the problem must be submitted to local District Recall Coordinator.

5.9 Termination of Recall

Recall should be terminated, after all possible customer responses have been received and it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed. A final status report and documentation of recalled product disposition must be provided to local District Recall Coordinator before FDA will consider formal termination of the recall action. The district office will notify the firm that FDA considered the recalls terminated.

Termination of Recall is notified to all affected parties, including domestic upstream customers, and international importers and customers for their their records and furter actions.



Standard Operating Procedure

TITLE: Final Pharmaceutical Product Recall

SOP: QA-211

Revision 006, 10/7/25

Page 6 of 6

6. APPROVALS

| | |
|----------------------------|---------------|
| _____ Originator | _____ Date |
| _____ Department Head | _____ Date |
| _____ Quality Assurance | _____ Date |

7. CHANGE HISTORY

| Revision# | Date | Reason for change |
|-----------|----------|---|
| 000 | 3/22/96 | Original |
| 001 | 12/19/96 | Added substitution and exchange criteria. |
| 002 | 1/28/04 | Revised under periodic SOP review |
| 003 | 05/28/04 | Added "Pharmaceutical" to title, purpose and scope statements. Changed all future tense verbs to present tense. Added detailed criteria related to recall process, including Recall Submission Process, Public Notification, Effectiveness of the Recall, Recall Status Report, Corrective and Preventive Actions, and Termination of Recall. |
| 004 | 2/21/19 | Added Solesence logo. |
| 005 | 1/9/21 | Updated SOP to include notification to Canadian importer. |
| 006 | 10/7/25 | Removed Nanophase name and replaced with Solesence |

Signature Manifest

Document Number: DOC-00354

Revision: 006

Title: QA-211 _Final Product Recall_

Effective Date: 08 Oct 2025

All dates and times are in Central Time Zone.

QA-211 _Final Product Recall_

Originator

| Name/Signature | Title | Date | Meaning/Reason |
|---------------------------|-----------------|--------------------------|----------------|
| Nataly Cochran (NCOCHRAN) | Quality Manager | 08 Oct 2025, 02:36:16 PM | Approved |

Department Head

| Name/Signature | Title | Date | Meaning/Reason |
|------------------|----------------------------|--------------------------|----------------|
| Nadir Ali (MALI) | Director, EH&S and Quality | 08 Oct 2025, 05:03:05 PM | Approved |

QA

| Name/Signature | Title | Date | Meaning/Reason |
|------------------|----------------------------|--------------------------|----------------|
| Nadir Ali (MALI) | Director, EH&S and Quality | 08 Oct 2025, 05:04:49 PM | Approved |