

|   |             |                          |
|---|-------------|--------------------------|
|  | RECALL PLAN | RP/FSM                   |
|   |             | Edition: 01              |
|   |             | Edition date: 04/15/2021 |
|   |             | Page 1 of 19             |

# nouns creamery

## Recall plan

**Done By:**

Beatriz De Lamo

**Updated By:**

Manan Bhagat

**Reviewed by:**

Louis Hristodoulou

**Accepted by:**

John Belesis

**CONTROL OF MODIFICATIONS**

| Edition | Date       | Modification   |
|---------|------------|--|
| 0       | 01/08/2018 | New document   |
| 1       | 04/15/2021 | Quality Organization chart updated(Manan Bhagat) and Annual Reassessment |
|         |            |  |
|         |            |  |
|         |            |  |
|         |            |  |
|         |            |  |
|         |            |  |

|   |                    |                            |
|---|--------------------|----------------------------|
|  | <b>RECALL PLAN</b> | RP/FSM                     |
|   |                    | Edition: 01                |
|   |                    | Edition date: 04/15/2021   |
|   |                    | Page <b>3</b> of <b>19</b> |

Nounós Creamery is committed to the manufacturing of safe and high-quality products that meet the highest safety, regulatory, and quality standards. In the event of a food safety issue arises with any of our products, this recall program will be put into action to identify and remove those products from circulation.

Nounós Creamery maintains a recall plan which provides specific procedures, defines terms, and assigns roles and responsibilities. It includes the following elements:

- Recall committee team and responsibilities.
- Recall procedures.
- Communication templates/records.

The Recall Plan shall be reviewed annually through a mock recall to ensure it functions effectively. It is also revised as necessary when personnel, procedures, processes, suppliers, or after any company recall.

## **1. PURPOSE**

The purpose of this recall plan is:

- Stop the distribution and sale of the affected product.
- Effectively notify Management, customers, SQFI (if SQF certified) and certification body regulatory authority (NY Department of Agriculture & Markets and FDA) of the recall.
- Efficiently remove the affected product from the marketplace.
- Remove the affected product from the warehouse and/or distribution areas.
- Dispose of the affected product.
- Conduct a root cause analysis and report the effectiveness and outcome of the recall.
- Implement a corrective action plan to prevent another recall.

|   |  |                          |
|---|--|--------------------------|
|  | <p style="text-align: center;">RECALL PLAN</p> | RP/FSM                   |
|   |  | Edition: 01              |
|   |  | Edition date: 04/15/2021 |
|   |  | Page 4 of 19             |

- Upon completion of the recall, management will conduct a post recall meeting to evaluate the recall.

## 2. SCOPE

A food recall is conducted to protect public health and safety. A food withdrawal is generally undertaken for quality purposes or as a precautionary measure before an official recall. This plan outlines the process for both a recall and a withdrawal.

## 3. DEFINITIONS

- Recall - A firm's removal or correction of a marketed product that the regulatory agency considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.
- Market Withdrawal - A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the regulatory agency or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
- Class I Recall – A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- Class II Recall - A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III Recall - A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.
- Disposition – The business’s action with respect to product to correct a situation leading to the recall, such as relabeling, recooking, reworking, or destroying product.

|   |  |                          |
|---|--|--------------------------|
|  | <p style="text-align: center;">RECALL PLAN</p> | RP/FSM                   |
|   |  | Edition: 01              |
|   |  | Edition date: 04/15/2021 |
|   |  | Page 5 of 19             |

- Retrieval – The removal of product at varying levels of the distribution system, store sales, or consumers’ homes depending on the seriousness of the problem.

#### **4. RESPONSABILITY**

The Recall Team is responsible for coordinating all aspects of the product recall.

#### **5. DESCRIPTION**

##### **5.1. RECALL PLAN ANNUAL REVIEW**

The recall plan must be review annually and after each recall, considering:

- Outcomes of mock (or practice) recalls.
- Outcomes of actual recalls and findings of post-recall reviews.
- Changes to the food business – including changes in products manufactured, staff or staff responsibilities, distribution networks, customers or suppliers.
- Feedback from recall training.
- Feedback from customers or changes in customer requirements.

##### **5.2. LIST OF FORMS REQUIRED FOR RECALLS**

- Recall distribution template (FO1/RP)
- Recall media template (FO2/RP)
- Recall notification (FO3/RP)
- If necessary: Voluntary recall template (FO4/RP)
- Effectiveness Log (FO5/RP)
- Effectiveness FDA Log (FO6/RP)
- Process Control record (FO3/PRP7)
- Receiving Log (FO1/PRP8)
- Sales Order Tracking Report (from *Fishbowl Inventory software*)

|   |  |                          |
|---|--|--------------------------|
|  | <p style="text-align: center;">RECALL PLAN</p> | RP/FSM                   |
|   |  | Edition: 01              |
|   |  | Edition date: 04/15/2021 |
|   |  | Page 6 of 19             |

### 5.3. Recall Team

The following Recall Team is responsible for coordinating all aspects of the product recall. All members must ensure that all procedures are carried out effectively and efficiently. The Recall Management Team list shall be updated at least once a year to ensure all names, contact phone numbers and responsibilities of team members are updated.

#### Recall Management Team

| RECALL COMMITTEE  |                          |              |   |
|---|--------------------------|--------------|---|
| Name  | Email                    | Phone number | Responsibilities during recall  |
| John Belesis<br>(President.<br>Director of<br>Operations) | john@nounoscreamery.com  | 5163592206   | <p><b>Recall team leader.</b></p> <p>Decision Making and recall strategy.</p> <p>Manage and coordinate the implementation of the product recall.</p> <p>Make sure all tasks are completed.</p> <p>Reassigns team members.</p> |
| Louis Hristodoulou<br>(Plant Manager)                     | louis@nounoscreamery.com | 5168517801   | <p><b>Government Liaison</b></p> <p>Communicates with regulatory agencies and works with legal counsel and provides information to regulatory agencies.</p>   |

|                                      |                             |            |  |
|--------------------------------------|-----------------------------|------------|--|
|                                      |                             |            | Submit status updated to the appropriate offices.  |
| Manan Bhagat<br>(QA Specialist)      | manan@nunoscreamery.com     | 4059222936 | <b>Recall team coordinator</b><br><br>Oversees complaint investigation. Prepare necessary information about the product.<br><br>Coordinate the recall team actions.  |
| Ken Dawes<br>(Production Supervisor) | ken.dawes@nunoscreamery.com | 5169245638 | <b>General assistant</b><br><br>Assist the team with prioritizing duties in the event of a crisis.<br><br>Substitute the Government Liaison and Recall Team Coordinator in the event she/ he is absent or occupied during a crisis |

**SUPPORT STAFF TO THE RECALL COMMITTEE**

| <b>Name</b>   | <b>Email</b>            | <b>Phone number</b> | <b>Responsibilities during recall</b>   |
|---|-------------------------|---------------------|---|
| Steven Ioanou<br>(Vicepresident. Director of Sales) | steve@nunoscreamery.com | 9172242411          | <b>Media/Customer Spokesperson</b><br><br>Handles all media and customer communication.<br><br>Works with regulatory agencies on press releases and customer letters. |
| Patty Yonkers                                       | patty@nunoscreamery.com | 5163756592          | N/A   |

|   |  |                          |
|---|--|--------------------------|
|  | <p style="text-align: center;">RECALL PLAN</p> | RP/FSM                   |
|   |  | Edition: 01              |
|   |  | Edition date: 04/15/2021 |
|   |  | Page 8 of 19             |

|                          |                           |            |     |
|--------------------------|---------------------------|------------|-----|
| (Accounting Manager)     |                           |            |     |
| Heather Medina (Finance) | heather@nunoscreamery.com | 6313526319 | N/A |

**REGULATORY AGENCIES**

|                                      |   |   |
|--------------------------------------|---|---|
| Federal Food and Drug Administration | New York district Recall coordinator:<br>- Maria Caride | 718-662-5577 (Ms. Caride)<br>718-662-5470 (LCDR Ruiz) |
|--------------------------------------|---|---|

|   |                    |                          |
|---|--------------------|--------------------------|
|  | <b>RECALL PLAN</b> | RP/FSM                   |
|   |                    | Edition: 01              |
|   |                    | Edition date: 04/15/2021 |
|   |                    | Page 9 of 19             |

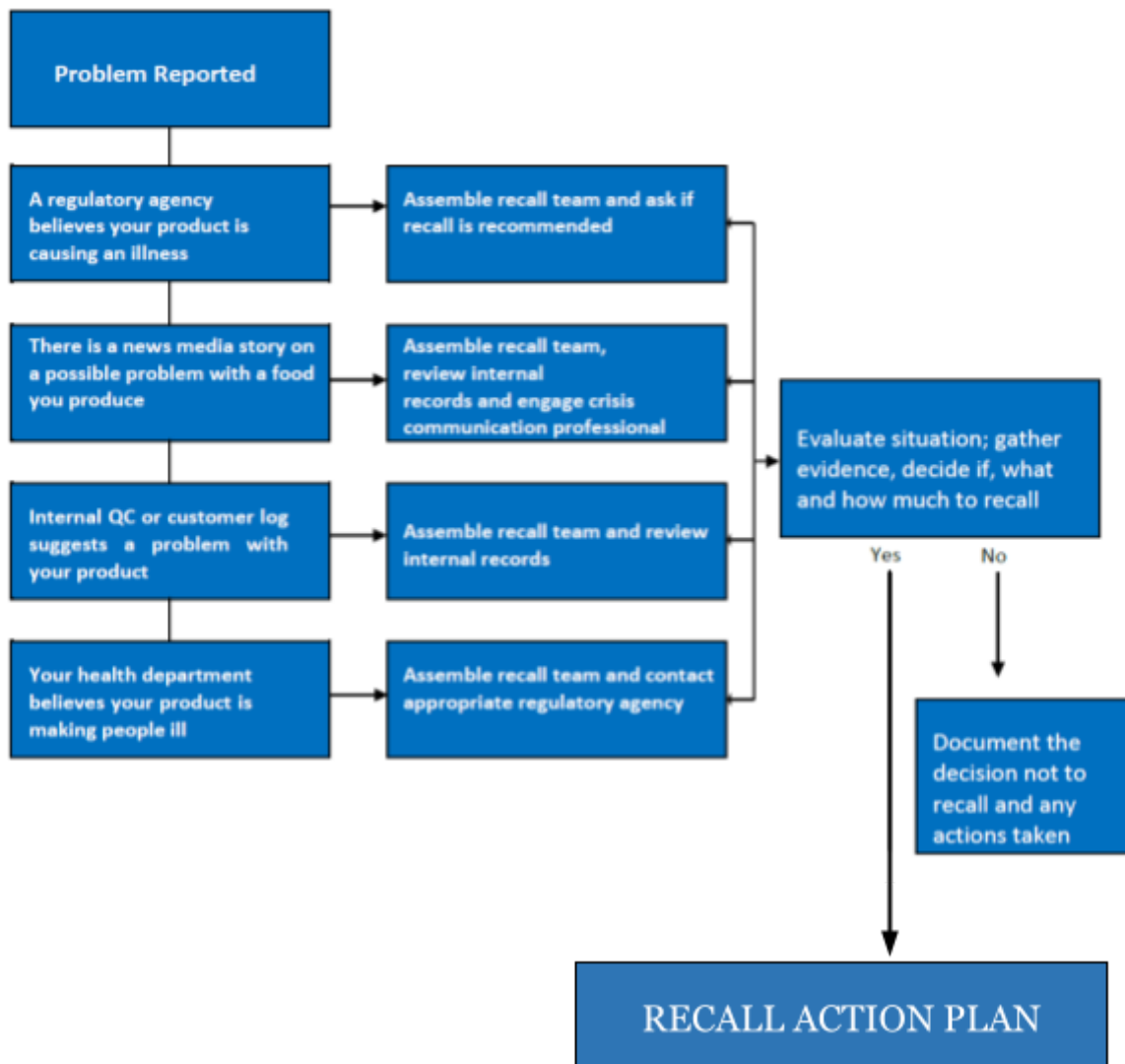
|                                    |  |  |
|------------------------------------|--|--|
|                                    | - LCDR Melinda Ruiz  | <i>FDA's emergency line at 1-866-300-4374 or 301-796-8240. The line is open 24 hours a day, every day of the week.</i> |
| New York Department of Agriculture | Inspector of the plant:<br>Kathy J. Laviolette<br>Jacqueline Burker<br>Mehgan Pleasant                       | 518- 457-8872 (Kathy J. Laviolette)<br>Jacqueline.Burke@agriculture.ny.gov<br>518-860-2491 (Mehgan Pleasant)           |
| SQFI                               | N/A  | foodsafetycrisis@sqfi.com  |
| Certification body: FSNS           | Zena Doty (Audit coordinator)  | <a href="mailto:FSNS-CAS@fsns.com">FSNS-CAS@fsns.com</a><br>zena.doty@fsns.com   |
| <b>OTHER</b>                       |  |  |
| Lawyer                             | Chuck Cotter<br>Partner, Holland & Hart LLP<br>1800 Broadway, Suite 300, Boulder, CO 80302<br>T 303.473.4832 |  |

#### **5.4. Determining if a Recall Action is necessary**

A recall may be initiated in a few ways:

- Consumer complaint(s).
- Notification by a regulatory agency of a food safety issue.

- An internal operations discovery or laboratory report indicating a potential food safety issue.



### 5.5. Traceability plan

Nounos Creamery uses a system that allows to trace products effectively one step forward and one step back. Our traceability plan can identify and quickly controlling potentially affected product and reconciling the quantities produced, in inventory, and distributed. We keep records of all our process and ingredients and assign our yogurts a traceability code (lot number) based on the day of production. See PRP11- Traceability.

|   |  |                          |
|---|--|--------------------------|
|  | <p style="text-align: center;">RECALL PLAN</p> | RP/FSM                   |
|   |  | Edition: 01              |
|   |  | Edition date: 04/15/2021 |
|   |  | Page 11 of 19            |

Fishbowl Inventory software is used to control the location and status of every part and product we have in our inventory system.

## MOCK RECALL

We conduct an annual mock recall exercise to determine the correct traceability of the final product, ingredients, and packaging material. The mock recall must be completed within 2 hours of initiation and must mimic the process of an actual recall to determine whether the recall plan and procedures are effective.

### 5.6. Recall classifications

- **Class 1:** When there is an emergency situation involving removal from the market of products in which the consequences of use or exposure to the product are life threatening or involve a serious adverse health consequence. Examples are: Listeria Monocytogenes, undeclared allergens, etc.
- **Class 2:** When there is a situation in which the use of, or exposure to, a violative product may cause temporary adverse health consequences or where the probability of serious adverse health consequence is remote. E.g., Pathogenic bacterial population, exclusive of C. botulinum, adequate to cause food poisoning, metal or glass fragments in a product.
- **Class 3:** When there is a situation in which the use of, or exposure to, the product is not likely to cause adverse health consequences. Example: labelling violations. Examples are: Misbranding of flavors (not using the term artificial), incorrect labeling type size and prominence, etc.

### 5.7. Recall steps

If the Recall Team Leader confirms that there is a true issue with the finished product, the Recall Team is to be convened as soon as possible.

In the event of a recall, the Recall Team Leader will take the following steps to ensure successful retrieval of products, communication with all necessary parties, and restoration of normal business:

|   |  |                          |
|---|--|--------------------------|
|  | <p style="text-align: center;">RECALL PLAN</p> | RP/FSM                   |
|   |  | Edition: 01              |
|   |  | Edition date: 04/15/2021 |
|   |  | Page 12 of 19            |

### 5.7.1. STEP 1. Assign Responsibilities.

Assemble the recall team to determine who will be responsible for each task.

### 5.7.2. STEP 2. Determine recall classification.

5.7.2.1. Conduct a thorough investigation into the problem with the affected product. Gather evidence and analyze them (lab results, customer complaints, etc.).

To determine the class and scope (class 1, 2 or 3) of the recall, nounós creamery will consider:

- Whether any disease or injuries have already occurred from use of the product.
- The seriousness of the health hazard.
- The immediate and long-range consequences.
- The ability to identify and quantify the defective product in the marketplace.

If the recall is due to a customer complaint, gather all information from the customer about the nature of the product complaint.

### 5.7.3. STEP 3. Identify all products to be recalled.

The Recall Team will collect all pertinent documentation regarding the affected Product. The Recall Team will use the *Recall Notification* (FO3/RP) to stay on track of all necessary steps in the recall process.

All products, ingredients and packaging material can be tracking by:

|   |  |                             |
|---|--|-----------------------------|
|  | <p style="text-align: center;">RECALL PLAN</p> | RP/FSM                      |
|   |  | Edition: 01                 |
|   |  | Edition date: 04/15/2021    |
|   |  | Page <b>13</b> of <b>19</b> |

- All Finished Products shipped can be tracked using *Fishbowl* and/or the *Process Control* Records (FO3/PRP7).
- All Work-In-Progress products can be tracked using *Process Control* Records (FO3/PRP7).
- All Ingredients received can be tracked by the *Receiving Log* (FO1/PRP8).
- All Packaging Material received can be tracked by the *Receiving Log* (FO1/PRP8).

The Recall Team Coordinator will initiate backward or forward traceability procedures to determine the products, number of units, date of production, expiration date and lot numbers involved.

#### 5.7.4. **STEP 4. Notify health agencies (FDA/USDA)**

Notify Regulatory Agencies at the earliest opportunity after the decision has been made to conduct a recall.

The Government Liaison member of the Recall Team will contact the country health department. If the issue is serious or life threatening, the Government Liaison will call the FDA’s 24-hour emergency line at 1-866-300-4374 or 301-796-8240.

The Government Liaison member will work with the Coordinator to make sure the required information is provided to the overseeing regulatory agencies throughout the investigation. The *Recall Notification* (FO3/RP) can be sent with all information.

|   |  |                          |
|---|--|--------------------------|
|  | <p style="text-align: center;">RECALL PLAN</p> | RP/FSM                   |
|   |  | Edition: 01              |
|   |  | Edition date: 04/15/2021 |
|   |  | Page 14 of 19            |

SQFI and the certification body shall be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification by the SQF practitioner. SQFI shall be notified at [foodsafetycrisis@sqfi.com](mailto:foodsafetycrisis@sqfi.com)

**5.7.5. STEP 5. Prepare a press release to the affected customers.** See *Recall Distributor Template (FO1/RP) AND Recall Media Template (FO2/RP), OR Voluntary Recall Template (FO4/RP).*

Press releases must include the following information:

- Product description with all relevant information: Lot numbers, yogurt name, expiration date and size.
- Recall the explanation.
- Hazard the product poses to the public.
- Contact information.

**5.7.6. STEP 6. Identify the location of the suspect product and prepare the distribution list.**

The Media/Customer Spokesperson member of the Recall Team will work with the overseeing regulatory agencies to send out all press releases and customer notifications. Nounós Creamery will notify all wholesale, retail, and direct customers as soon as possible about the recall. Notifications will be done through a telephone call, in person, website and/or in writing (the preferred form of notification). Never via paper mails.

*NOTE: Notification of customers is required for Class 1 recalls. It could be needed for class 2 recalls if there is a threat to public health. Decisions*

|   |  |                          |
|---|--|--------------------------|
|  | <p style="text-align: center;">RECALL PLAN</p> | RP/FSM                   |
|   |  | Edition: 01              |
|   |  | Edition date: 04/15/2021 |
|   |  | Page 15 of 19            |

*on when notification is necessary can be determined through discussions with FDA.*

A complete distribution list of all businesses that have received the affected product will be compiled (with as much detail as possible), including:

- each business’s name, address, contact person, phone numbers.
- the quantity of affected products in each location.
- the types of premises where the product has been sold (e.g. supermarkets or specialty grocers).

This list can be found in Fishbowl.

**5.7.7. STEP 7. Detain and segregate all products to be recalled which are in the firm** to prevent reentry into the commerce stream.

**5.7.8. STEP 8. Submit samples** of recalled product(s) to the New York Department of Agriculture and independent laboratory for testing.

**5.7.9. STEP 9. Remove recalled products.**

The Recall Coordinator or a designated member of the Recall Team is responsible for ensuring all recalled products are controlled and disposed of appropriately. Nounós Creamery will work with the overseeing regulatory agencies to decide on the appropriate disposition of recovered recalled products. The Recall Coordinator or another member of the Recall Team will document quantities, identification codes, and disposition.

Method of retrieval

|   |                    |                          |
|---|--------------------|--------------------------|
|  | <p>RECALL PLAN</p> | RP/FSM                   |
|   |                    | Edition: 01              |
|   |                    | Edition date: 04/15/2021 |
|   |                    | Page 16 of 19            |

Customers (retailers, distributors, wholesalers, etc.) will be advised what to do with recalled product, including to:

- separate recalled product from other food and identify it as subject to recall AND
- count and return the product for disposal or count and dispose of the product themselves.
- Retrieved product being held for disposal will be separated from other food and clearly identified as being subject to recall.
- All recalled products will be accounted for, by recording what stock is retrieved and what stock (if any) is disposed of by customers.

Method of disposal

The business will choose how to dispose of the recalled product in consultation with the home state (if required), from the following options:

- destroy or treat the product in another way (e.g. denature) so that it cannot be used for human consumption and place it in the rubbish.
- further process the product to ensure that it is safe and suitable for human consumption (e.g. by re-labelling or re-processing).
- use for purposes other than human consumption (e.g. animal feed, if appropriate).
- return to the supplier.

|   |  |                          |
|---|--|--------------------------|
|  | <p style="text-align: center;">RECALL PLAN</p> | RP/FSM                   |
|   |  | Edition: 01              |
|   |  | Edition date: 04/15/2021 |
|   |  | Page 17 of 19            |

**5.7.10. STEP 10. Verify the effectiveness of the recall.**

The team will document effectiveness checks of the recall in *Effectiveness log* (FO5/RP) and *Effectiveness log* FDA (FO6/RP) to prove that all affected consignees have been notified and have taken the appropriate action.

The following method will be used to know the effectiveness of the recall:

A – Total amount of product produced

B – Amount still on inventory

C – Lost

D – Amount delivered to customers

E – Incidental usage (lab samples, cooler dump, etc.)

$$\frac{B + C + D + E}{A} \times 100 = \% \text{ Effectiveness}$$

**5.7.11. STEP 11. Terminate the recall.**

The decision to terminate the recall will be made once it has been deemed successful, based on: the risk to the public is judged to be minimal and the business has taken all reasonable steps to ensure the effective recall.

The Recall Team will evaluate whether all possible customer responses have been received and if it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed.

The Recall Team will submit a written request to the appropriate Food and Drug Administration district office stating that the recall is effective. Staff and business customers should be informed of the recall's termination.

|   |  |                          |
|---|--|--------------------------|
|  | <p style="text-align: center;">RECALL PLAN</p> | RP/FSM                   |
|   |  | Edition: 01              |
|   |  | Edition date: 04/15/2021 |
|   |  | Page 18 of 19            |

**5.7.12. STEP 12. Statement announcing the end of the recall**

Upon completion of a recall, the Media/Customer Spokesperson member of the Recall Team will craft a statement announcing the end of the recall to advise customers that they may once again enjoy our products.

**5.7.13. STEP 13. Debrief.**

Set up a meeting with the recall team to discuss the recall.

**5.7.14. STEP 14. Fix the cause of the recall** if the problem occurred at our facility.

**5.7.15. STEP 15. Reanalysis of Food Safety Plan.**

Corrective action to ensure that the same recall does not happen again. The plan may need modification, and/or employees may need to be retrained to enhance the implementation effectiveness.

**6. MONITORING AND VERIFICATION**

Nounós Creamery carries out at least a mock recall per year in order to evaluate the product recall program.

**7. CORRECTIVE ACTIONS**

- Modify the recall plan to correct any problems encountered during mock recall
- Reanalyze the food safety plan

**8. DOCUMENTS**

N/A

**9. RECORDS**

- Fo1.RP/FSM. Ed 00 01/08/2019. Recall distributor template.
- Fo2. RP/FSM. Ed 00 01/08/2019. Recall media template.

|   |             |                             |
|---|-------------|-----------------------------|
|  | RECALL PLAN | RP/FSM                      |
|   |             | Edition: 01                 |
|   |             | Edition date: 04/15/2021    |
|   |             | Page <b>19</b> of <b>19</b> |

- F03.RP/FSM. Ed 00 01/08/2019. Recall notification.
- F04.RP/FSM. Ed 00 01/08/2019. Voluntary recall template.
- F05.RP/FSM. Ed 00 01/08/2019. Effectiveness log.
- F06.RP/FSM. Ed 00 01/08/2019. Effectiveness FDA log.