DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Recall Procedure for Dietary Supplements	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1. **Purpose:** This Standard Operating Procedure (SOP) describes in detail the recall procedure for Dietary Supplements.

2. **Scope:** This SOP is applicable to hold and/or recall of Dietary Supplements from distribution or market due to certain non-confirmatory aspects or instruction from FSSAI.

3. **References and Attachments:**
   - **3.1. References:**
     - **3.1.1.** SOP: Handling of Market Complaints
   - **3.2. Attachments:**
     - **3.2.1.** Attachment 1 - Recall classification and associated actions with time lines.
     - **3.2.2.** Attachment 2 - Recall register (To be maintained at location)
     - **3.2.3.** Attachment 3 - Recall register (To be maintained at CQ)
     - **3.2.4.** Attachment 4 - Recall register (To be maintained at distribution)
     - **3.2.5.** Attachment 5 - Example of recall authorization request
     - **3.2.6.** Attachment 6 - Example for preparation of rational for recall.
     - **3.2.7.** Attachment 7 - Example of letter to be used for Type A recall by distribution.
     - **3.2.8.** Attachment 8 - Example of letter to be used for Type B recall by distribution.
     - **3.2.9.** Attachment 9 - Example of recall effectiveness check letter to consignee.
     - **3.2.10.** Attachment 10 - Example of recall effectiveness response (Mail method)
     - **3.2.11.** Attachment 11 -Example of recall effectiveness response (Telephone & personal visit method).
     - **3.2.12.** Attachment 12 - Example of recall termination letter.
     - **3.2.13.** Attachment 13 - Example of recall periodic status/final report.
     - **3.2.14.** Attachment 14 - Example of mock recall audit report.
   - **3.3. Annexures:** NA

4. **Responsibilities:**
   - **4.1. Head Quality Assurance:**
     - **4.1.1.** To recommend the recall of dietary supplements.
     - **4.1.2.** To arrange for destruction of recalled dietary supplements as per SOP.
     - **4.1.3.** To ensure proper documentation.
   - **4.2. Head Quality:**
     - **4.2.1.** To authorize the hold and /or destruction authorization request.
     - **4.2.2.** To monitor the activity as per SOP.
     - **4.2.3.** To monitor implementation of corrective/preventive action(s) as per the recommendation(s).
   - **4.3. Factory Head:**
     - **4.3.1.** To authorize hold and /or destruction authorization request.
     - **4.3.2.** To monitor the activity as per SOP.
     - **4.3.3.** To monitor implementation of corrective/preventive action(s) as per the recommendation(s).
   - **4.4. Corporate Quality:**

4.4.1. To provide hold &/or recall registration number.
4.4.2. To review hold &/or recall authorization form.
4.4.3. To intimate marketing/distribution for retrieval of dietary supplements from market.
4.4.4. To monitor implementation of corrective/preventive action(s) as per the recommendation(s).

4.5. Head Corporate Quality:
4.5.1. To decide on recall request of dietary supplements.
4.5.2. To intimate FSSAI.
4.5.3. To verify the recalled quantity against the distributed quantity and reconcile with quantity dispatched.
4.5.4. To communicate R & D if require.
4.5.5. To perform mock recall for evaluation of effectiveness of the recall procedure.

4.6. Distribution:
4.6.1. To hold the stock for further distribution at respective consignee.
4.6.2. To provide the stock available at respective consignee.
4.6.3. To retrieve the hold product at company's central warehouse.
4.6.4. To intimate corporate quality for retrieval.

5. Distribution:
5.1. Distribution
5.2. QA

6. Definition of terms & Abbreviations:
6.1. Definition of terms:
6.1.1. Recalls: A recall may be defined as the retrieval from the marketplace of a batch/es of a dietary supplements as a result of a quality defect or other issue being identified with the batch/es which resulted in the batch/es not to be in compliance with the terms of the product marketing authorization. In addition, a product recall may be warranted due to the emergence of new safety information relating to a product or class of products.

6.1.2. Correction: Repair, modification, adjustment, relabeling, destruction or inspection of dietary supplements without physical removal.

6.1.3. Recalling firm/Manufacturing location /Location: The firm who has produced / manufactured/marketed the dietary supplements (under distribution or in use) being recalled.

6.1.4. Consignee (C & F agent/Distribution depot/Stockist): Anyone who receives and further distributes the dietary supplements.

6.1.5. Market withdrawal: A firms removal or correction of a distributed dietary supplements which involves a minor violation that would not be subject to legal action by the food safety and standard authority of India or which involves no violation, e.g. Normal stock rotation practices, routine equipment adjustments/repairs etc.

6.1.6. Stock recovery: A firm's removal or correction of a dietary supplements that has not been marketed or that has not left the direct control of the firm, i.e. The dietary

supplement is located on premises owned by or under the control of the firm and no portion of the lot has been released for sale/use.

6.2. Abbreviations:

6.2.1. FSSAI - Food Safety and Standard Authority of India.
6.2.2. CQ - Corporate quality department.
6.2.3. RA - Regulatory affairs department.
6.2.4. R & D – Research and Development
6.2.5. PIC – Pharmaceutical Inspection Convention
6.2.6. PIC's – Pharmaceutical Inspection Cooperation Scheme
6.2.7. C & F – Clearing & Forwarding

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7. Procedure:

7.1. Recall initiation:

7.1.1. Initiation of a dietary supplement recall may be voluntary or FSSAI requested or FSSAI mandated.

7.1.2. Dietary supplement hold and recall may trigger due to any of the below reasons.

7.1.2.1.
On confirmation of quality complaint which may be from customer/FSSAI/external sources or agencies. Examples of such complaints are following but not limited to those.

7.1.2.1.1.
Ineffectiveness.
7.1.2.1.2.
Foreign matter.
7.1.2.1.3.
Color change.
7.1.2.1.4.
Change in physical form
7.1.2.1.5.
Adverse reaction/event
7.1.2.1.6.
Stability failure
7.1.2.1.7.
Mislabeling observed

7.2. Product recall classification:

7.2.1. Type A (US Class -I or PIC/s Class I & II): Recall from consumer/retailer/ pharmacy / stockiest level where there **is a risk** to customer's health.

7.2.1.1.
US Class-I: is a situation in which there is a reasonable probability that
the use of, or exposure to, a violative dietary supplement will cause serious adverse health consequences or death.

7.2.1.2.
IC/s Class-I: defects are potentially life threatening. A rapid alert notification must be sent to all parties.

7.2.1.3.
IC/s Class-II: Defects could cause illness or mistreatment, but are not Class I. A rapid alert notification should be sent only to those parties to which it is known, or believed, that the batch has been distributed. In the case of parallel imports where there is difficulty in establishing the traceability of batches, consideration should be given to notifying all parties by the rapid alert system.

7.2.2. Examples of PIC/s-Class I defects include following but not limited to those.

- Wrong dietary supplement (label and contents are different dietary supplements)
- Correct dietary supplement but wrong strength, with serious medical consequences.
- Chemical contamination with serious medical consequences
- Mix-up of some dietary supplement with more than one container involved
- Wrong active ingredient in a multi-component dietary supplement, with serious medical consequences.

1.1.1. Examples of PIC/s-Class II defects include following but not limited to those.

- Mislabeling, e.g. wrong or missing text or figures.
- Missing or incorrect information (leaflets or inserts)
- Chemical/physical contamination (significant impurities, cross-contamination, particulates).
- Mix up of dietary supplements in containers.
- Non-compliance with specification (e.g. assay, stability, fill/weight).

1.1.1. Type B (US Class II/III or PIC/s Class III): Recall from stockiest where there is **no risk** to customer's health.

1.1.1.1.
Class II is a situation in which use of, or exposure to, a violative dietary supplement may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

1.1.1.2.
PIC/s Class -III: Defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons. These are not notified through the rapid alert system.

1.1.1.3.
Examples of Class III defects include following but not limited to those.

- Faulty packaging, e.g. wrong or missing batch number or expiry date.
- Contamination, e.g. microbial spoilage, dirt or detritus, particulate matter of oral dosage form.

1.1. Time lines and actions associated with recalls:

1.1.1. The time lines and actions associated with the above classes of recalls are summarized in **Attachment-1.**

1.2. Required information for recall:

1.2.1. Location shall be having following information for dietary supplement recall.

- Name of authorized local District Recall Coordinator.
- A consignee list (names/address/city/state/contact name/phone number).
- A list of customers and FSSAI consignees.

1.1.1. Contacts for Recalling Firm:

- Name/title/phone/fax number/e-mail address for RECALL contact.
- Name/title/address/phone/fax number of the most responsible individual for the recalling firm.
- Name/title/phone/fax number/e-mail address for public contact.

1.1.1. Recalling Firm:

- Firm name, address, city, state, zip code.
- Firm type (i.e. manufacturer, importer, broker, re packer, own-label distributor).

1.1. Hold, recall and destruction procedure for Dietary supplements:

1.1.1. In case of dietary supplement failure which may be due to any of the above reasons, location shall make necessary entries in dietary supplement recall register as per **Attachment-2** and shall inform to CQ through e-mail and shall collect product hold & recall registration number from CQ.

1.1.2. CQ shall make necessary entries in product hold & recall register as per **Attachment-3.**

1.1.3. Hold & recall registration number at CQ shall be defined as CHR/12/01 where CHR stands for hold and recall, 12 for year 2012 and 01 is serial number.

1.1.4. Location shall send approved soft file of "hold and recall authorization request" to CQ as per **Attachment-5** along with the rational as per **Attachment-6** or investigation report containing rational for hold/recall.
Note: Investigation report must include Impact analysis: Inspection/analysis of samples of other batches.

1.1.5. CQ shall review the request and shall take approval from head CQ for further actions depending upon the nature of the problem. Further actions may include following but not limited to those.

- Holding of the further distribution of the dietary supplement batch.
- Inspection/analysis of samples of different distribution locations.
- Withdrawal of stock.
- Refusal of hold &/or recall request.

1.1.1. Head CQ shall comment /suggest /approve the recall authorization request.

1.1.2. Copy of the approved/commented request shall be sent to location with copy to FSSAI, MD office, and distribution / marketing department.

1.1.3. If recommendations/comments given through mail, copy of the same shall be attached with hold & recall authorization request **Attachment -5.**

1.1.4. In case of approval of the hold and recall authorization request, CQ shall instruct distribution (with copy to FSSAI and MD office though e-mail & phone if required) to hold and/or recall the batch/es and to provide the stock status through e-mail if required.

1.1.5. Distribution shall provide the stock status available at respective stockist on the same day. (preferably within 2 hrs).

1.1.6. CQ shall collect samples form different stockiest/C&Fs and shall send them to respective location for the inspection/testing (for critical quality parameters) if recommended in hold & recall request.

1.1.7. If required, a representative from concerned location may visit the respective Consignee(s) within 02 working days after receipt of stock status and withdraw the samples and arrange for analysis for further investigation.

1.1.8. In case of type B recall, if CQ has recommended sampling, inspection, analysis of samples of different distribution locations (Stockiest/C&Fs), location shall take actions accordingly and shall send report to CQ having action taken, analysis results, impact analysis etc. within 03 working days after receipt of the samples.

1.1.9. In case of rejecting the hold and recall authorization of the batch/es, proper justification shall be included by CQ head.

1.1.10. CQ head shall give instruction to distribution where to recall and destroy the batch in question.

1.1.11. In case of type A recall, distribution shall instruct different C&F /stockiest to recall the batch up to stockist as well as dealers, distributors, wholesalers and retailer level through mail as per **Attachment-7.**

1.1.12. Distribution shall send the proofs of such communications & acknowledgments of the same received from dealers, distributors, wholesalers and retailer to concerned location.

1.1.13. In case of Type A recall rapid alerts to consumer level shall be given through television, radio, newspapers etc in consultation with FSSAI.

1.1.14. In case of Type B recall, distribution shall instruct different C & F/stockiest to recall the batch up to stockist level through mail as per **Attachment-8.** Copy of the e-mail or proofs of such communications shall be sent to concerned location with copy to CQ.

1.1.15. Location shall ensure hold and recall of the dietary supplements as per time lines given in **Attachment-1.**

1.1.16. Location shall ensure that recalled dietary supplements is stored at the designated area ensuring security, storage condition and segregation.

1.1.17. Location shall verify the quantity of recalled/recovered stock against hold stock status & shall make necessary entries in dietary supplements hold & recall register as per **Attachment-2.**

1.1.18. Location shall arrange destruction of the batch as per location SOP in the presence of QA.

1.1.19. In case if the recall & destruction is recommended at destruction location, the same shall be done in presence of location QA representative & necessary destruction details/procedure shall be recorded by location representative as per **Attachment-2.**

1.1.20. CQ shall monitor that hold and recall actions are taken as mentioned in **Attachment-1.**

1.2. Assessing Recall Effectiveness:

1.2.1. The purpose of effectiveness checks is to verify that all consignees have received notification about the recall and have taken appropriate action. The method for

contacting consignees may be accomplished by personal visits, telephone calls, letters, mails or a combination thereof.

1.2.2. CQ shall evaluate the effectiveness of the recall procedure from the actual recall or by performing type B mock recall as per the procedure given in current CQ guideline on Recall and prepare the evaluation report.

1.2.3. Type A & Type B mock trail(s) and/or actual recall(s) shall be performed/ evaluated once in a year ±1 month.

1.2.4. Procedure for Type A mock product recall:

1.2.4.1.

CQ shall collect following information/batch detail through mail for atleast three products from more than one location.

1.2.4.1.1.
Product name & strength.

1.2.4.1.2.
Batch number.

1.2.4.1.3.
Manufacturing and expiry dates.

1.2.4.1.4.
Pack presentation.

1.2.4.1.5.
Total qty. of batch dispatched.

1.2.4.1.6.
Date of dispatch.

1.2.4.1.7.
Dispatched to.

1.2.4.2.

Locations shall provide the requested batch details to CQ.

1.2.4.3.

CQ shall inform the head of distribution department to provide below information about the selected batches and to hold the stock at various retailers.

1.2.4.3.1.
List of retailers to whom the batch/es are distributed.

1.2.4.3.2.
Qty. of the batch sold to each retailer.

1.2.4.3.3.
Stock status at each retailer.

1.2.4.4.

CQ shall inform to the head of distribution department to hold the stock of the selected batches requesting the stock status at various distribution depots.

1.2.4.5.

Distribution shall hold the stock of the products and shall provide the requested details and stock status at various distribution depots and retailers.

1.2.4.6.
Distribution head shall directly communicate to retailers or may take help of the distribution depots to hold the stock and collect the stock status.

1.2.4.7.
CQ shall ensure that stock details and confirmation about the holding of the stock from the distribution depots is received within one day through distribution head through e-mails. (time starts after sending the batch details to distribution).

1.2.4.8.
CQ shall ensure that stock details and confirmation about the holding of the stock at selected retailer is received from the distribution within two days through e-mails. (time starts after sending the batch details to distribution).

1.2.4.9.
CQ shall ensure that selected retailers have responded within defined time line. The retailer may respond to distribution telephonically or through e-mail.

1.2.4.10.
CQ shall visit the two or three (Consignee) distribution depots and shall verify the stock of the product/s against stock status received from distribution head along with product storage condition and security of the hold product. The details of audit shall be recorded as per **Attachment-14.**

1.2.4.11.
CQ shall prepare the mock product recall report and conclude the effectiveness of the recall.

1.2.4.12.
CQ shall circulate the report to distribution as well as locations for record with copy to CQ head.

1.2.5. Procedure for Type B mock product recall:

1.2.5.1.
CQ shall collect following information /batch detail through mail for at least three products from more than one location.

1.2.5.1.1.
Product name & strength.

1.2.5.1.2.
Batch number.

1.2.5.1.3.
Manufacturing and expiry dates.

1.2.5.1.4.
Pack presentation.

1.2.5.1.5.
Total qty. of batch dispatched.

1.2.5.1.6.
Date of dispatch.

1.2.5.1.7.
Dispatched to.

1.2.5.2.
Locations shall provide the requested batch details to CQ.

1.2.5.3.
CQ shall inform to the head of distribution department to hold the stock of the selected batches requesting the stock status at various distribution depots.

1.2.5.4.
Distribution shall hold the stock of the products and shall provide the requested details and stock status at various distribution depots.

1.2.5.5.
CQ shall ensure that stock details and confirmation about the holding of the stock from the distribution depots is received within one day through distribution head through e-mails. (time starts after sending the batch details to distribution).

1.2.5.6.
CQ shall visit the two or three (Consignee) distribution depots and shall verify the stock of the product/s against stock status received from distribution head along with product storage condition and security of the hold product. The details of audit shall be recorded as per **attachment-14.**

1.2.5.7.
CQ shall prepare the mock product recall report and conclude the effectiveness of the recall.

1.2.5.8.
CQ shall circulate the report to distribution as well as locations for record with copy to CQ head.

1.3. Recall status reports/Recall final report:

1.3.1. Periodic status reports shall be prepared by the recalling firm on the progress of the recall effectiveness checks at **biweekly intervals**. These recall status reports shall contain following information.

- Number of consignees notified of the recall, and date and method of notification.
- Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
- Number of consignees that did not respond.
- Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
- Number of consignees contacted as per level and results of effectiveness checks that were made.
- Estimated time frames for completion of the recall.
- Corrective action plan.

1.1.1. In case of domestic product, these periodic status reports should be addressed to CQ.

1.1.2. A final report on recall shall be prepared including reconciliation between the delivered and recovered quantities of the products.

1.1.3. The report shall be sent to CQ for recall termination within 35 working days after recall at location. The final report should include CAPA.

1.1.4. **Correction and preventive Action Plan** (CAPA) should include following

- Description.
- Consignee list.
- Description of the defect (including all reports, documents, memos, etc., of meetings, technical reviews, etc., which pertain to the analysis of the problem).
- Proposed steps to be taken to correct the dietary supplements in the field and steps taken to prevent future occurrences.
- Proposed effectiveness checks to be conducted.
- Proposed date of completion and appropriate interim dates for implementation of the correction.
- Any and all injury/death investigations or reports.
- Pertinent complaints on file.

1.1.1. If product recall is due to stability failure CQ shall intimate R & D and co-ordinate in resolving the dietary supplement problem.

1.1.2. The recalling firm shall issue CAPA to concerned for the same.

1.2. Recall termination: Termination of a domestic product recall: Type A/Type B

1.2.1. Upon receipt of the final recall report, CQ shall evaluate the same with respect to efforts put to recover the dietary supplements, quantity delivered v/s quantity recovered and shall approve the recall termination request as per **Attachment -12** within **03 working days** after receipt of the report.

1.2.2. In-case of type B recall, recall shall be terminated after ensuring recall of 100% quantity of the stock status from consignee to location.

1.3. Product destruction/corrections:

1.3.1. The recalling firm and consignee should keep adequate documentation of dietary supplements destruction (and whether or not destruction was witnessed by an FSSAI investigator).

1.3.2. Field corrections, (i.e. product relabeling), should be performed by recalling firm representatives, or under their supervision and control.

1.3.3. It is not recommended that a disinterested party such as a wholesaler or retailer be responsible for field corrections.

Attachment 1

RECALL CLASSIFICATION AND ASSOCIATED ACTIONS WITH TIMELINES

Recall classification	Type A (US Class -I or PIC/s Class I & II)	Type B (US Class II / III or PIC/s Class III)
Time period for holding the stock (Time starts after receipt of the recall request from location)	Domestic & Export: Within 01 day upto stockist level. Within 02 days upto retailer level.	Domestic & export: Within 02 working days
Time period for recall. (Time starts after receipt of the recall request from location)	Domestic: Within 03 working days upto stockist level. Within 05 working days upto retailer level. Export: Within 05 working days upto stockist & retailer level.	Domestic & export: Within 07 working days - **OR** Within 30 working days – Incase if biological assay required.
Method of Notification to distribution and FSSAI	Phone & fax, Radio/Television /e-mail/ Newspapers (if necessary), press announcements followed by letter.	Phone / fax / mail / letter/e-mail.
Extent of Notification	Wholesalers, pharmacies and professional groups, customers, other retailers.	Stockist, pharmacies, hospitals.
Method of retrieval of recalled stock.	Direct uplift of stock &/or via stockist.	Via stockist.

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Attachment - 2

RECALL REGISTER

(TO BE MAINTAINED AT LOCATION)

Recall No.	Dietary Supplement Name	B. No.	Reason for recall	Type of recall (Type-A/B)	Total Qty. dispatched to distribution.	Qty. recalled from distribution	Recalled on	Destruction details				CAPA (CAPA no.)	CAPA status (Open/close)	Details entered by	Checked by
								Qty.	Date	Destroyed by	Checked by/ Date				

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Attachment – 3

RECALL REGISTER
(TO BE MAINTAINED AT CQ)

Recall No.	Mfg. Location	Product	B.No.	Reason for recall	Type of recall (Type-A/ Type-B)	Date of recall approval received	Informed to distribution on date	Total Qty. dispatched to distribution	Qty. recalled from distribution	Qty. destroyed on	CAPA (CAR no.)	CAPA status (Open/close)	Details entered by	Checked by

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Attachment – 4

RECALL REGISTER
(TO BE MAINTAINED AT DISTRIBUTION)

Recall No.	Product	Batch No.	Reason for recall	Date of recall intimation received.	Type of recall (Type-A/Type-B)	Qty. dispatched to different Consignee.			Qty. recalled from different Consignee.			Qty. sent to location	Sent by /Date
						1	2	Total	1	2	Total		

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Attachment – 5
EXAMPLE OF HOLD AND RECALL AUTHORIZATION REQUEST

For location quality use:

From : Quality Assurance — Recall No.: HR/ Year/ Sr. no.____

To : Corporate quality — Date : _____

Please authorize to hold the stock of following dietary supplements in the market.

S.No	Dietary Supplement details								Dispatch details			Hold for type of recall (Type A /Type B)	Reason for Hold
	Brand &/or generic name	Strength	Dosage form	Marketing authorization number	Pack size and presentation	Batch No	Mfg. dt	Exp. dt	Batch size	Qty	Date	Dispatched to		

Initiated by

Head quality assurance: Cont….

Date:

Approved by

Head location quality: Factory head:

Date: Date:

For corporate quality use:

The hold and recall request received by :_____on date _____.

Recommendations from corporate quality:

Prepared by: _____ Date:_____

Approved by:

Head Quality: Head regulatory: VP – Quality:

Date: Date: Date:

Copy to:

Head distribution.

MD office

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Attachment – 6
EXAMPLE FOR PREPARATION OF RATIONAL FOR RECALL
Rational for product recall

S.No.	Investigation check points	Investigation details
1	Explain in detail how the product is defective/or violative.	
2	Explain how the defect effects the performance and safety of the product.	
3	If the recall is due to presence of a foreign object, describe the foreign object's size, composition, hardness, and sharpness.	
4	If the recall is due to presence of contaminant (cleaning fluid, machine oil, paint vapors), explain level of contaminant in the product .Provide labeling, a list of ingredients and the material safety data sheet for the contaminant.	
5	If recall is due to failure of the product to meet specification, provide the specifications and report all test results. Provide copies of any sample analysis.	
6	If recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s)	
7	Explain how the problem occurred and the date(s) it occurred.	
8	Explain how the problem was discovered and the date discovered.	
9	Explain if the problem /defect all units subject to recall, or just a portion of the units in the lots subject to recall.	
10	Explain why this problem affects only those products/lots subject to recall.	
11	Provide detailed information on complaints associated with the product problem.	
12	Date of complaint.	
13	Description of complaint- include details of any injury or illness.	
14	Lot Number/Serial number involved.	

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Attachment – 7

EXAMPLE OF LETTER TO BE USED FOR TYPE A RECALL BY DISTRIBUTION

Date _____

Subject **: Recall of following batches of _____ (Company)**

This is to inform you that dietary supplements as per the details given below were sold to you:

Date	Invoice #	Dietary Supplement	Batch #	Strength	Pack presentation	Quantity

We have decided to urgently recall from stockist the above batches of this dietary supplements due to following reasons.

1.
2.
3.

We have decided to urgently recall from the market the above batches of this dietary supplements Therefore, kindly send the stocks of the batches with you to us, on most urgent basis.

Further you are also requested to send similar letter as above, to the dealers, distributors and wholesales, to whom you have supplied and sold the above batches and intimate them to urgently return the stocks, if available with them, to you, and if any stocks are received by you, the same may please be sent to us on top priority basis. If you get the stocks in due course of time, the same may subsequently be sent to us as early as possible.
The receipt of this recall letter may please be acknowledged.

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Attachment-8

EXAMPLE OF LETTER TO BE USED FOR TYPE B RECALL BY DISTRIBUTION

Date _____

Subject**: Recall of following batches of _____(company)**

This is to inform you that dietary supplements as per the details given below were sold to you:

Date	Invoice #	Dietary Supplements	Batch #	Strength	Pack presentation	Quantity

We have decided to urgently recall from stockist the above batches due to following reasons.

1.

2.

3.

Therefore, kindly send the stocks of the batches with you to us, on most urgent basis.

The receipt of this recall letter may please be acknowledged.

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Attachment-9

EXAMPLE OF RECALL EFFECTIVENESS CHECK LETTER TO CONSIGNEE

Consignee Name and Address Date

Dear Sir:

On (date), you were notified by letter that _____ Company, Someplace, Somewhere 12345, is recalling (dietary supplements name), container size, code number.

All dietary supplements were manufactured by _____ Company and distributed solely under the manufacturer's label.

Recall of the dietary supplement was initiated following a change in their formulation which resulted in dietary supplements in distribution channels having the same brand name but different ingredients.

The old formulation contained X and there is concern that consumers may receive the old formula. Use of the old formulation by some consumers represents a potential health hazard.

The recall notice from _____ Company requested consignees (wholesalers and retailers) to discontinue selling their existing stock of the old formulations and return existing inventories of the recalled formulations to _____ Company.

In order to advise the Food Safety and Standard Authority of India, about the effectiveness of this ___ Company recall, you are requested to complete and return the enclosed questionnaire promptly using the prepaid self-addressed envelope.

If you have any questions or problems with this request, please call (name and telephone number).

Thank you for your cooperation.
Sincerely,

NOTE: If this letter is sent to distributors who may have further sold the dietary supplements to other distributors or to retail outlets, the third paragraph should include the fact that the recall notice requested the direct consignees to conduct sub-recalls by notifying their customers of the recall situation.

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Attachment-10
EXAMPLE OF RECALL EFFECTIVENESS CHECK RESPONSE
(MAIL METHOD)

Consignee Name and Address
Recall effectiveness checks-Mail Method
_____ (Company name) RECALL

PLEASE READ EACH QUESTION AND CHECK THE PROPER ANSWER YOU HAVE CHOSEN
PLEASE CHECK WITH ANYONE WHO MAY HAVE RECEIVED THIS NOTIFICATION BEFORE ANSWERING.

DATE_____

- Did your firm receive notification that the _____ Company is recalling its (Name) dietary supplements?
  - YES/NO
- Did your firm receive shipments of the dietary supplements being recalled?(If no, please sign and return).
  - YES/NO
- Do you now have any of the recalled dietary supplements on hand? (Please check inventories before answering).
  - YES /NO
- If the answer to question 3 is YES, do you intend to return the dietary supplements to the John Doe Company as requested?
  - YES /NO
- If the answer to question 4 is NO, please explain your intentions.
- Have you received any reports of illness or injury related to this dietary supplements?
  - YES /NO

  If yes, please provide details.
  Name of person completing questionnaire:
  Consignee Name and Address,

Attachment – 11

EXAMPLE OF RECALL EFFECTIVENESS CHECK RESPONSE (TELEPHONIC & PERSONAL VISITS METHOD)

Recall effectiveness checks-
Telephone and Personal Visits method

_____(Company name) RECALL

After contacting the consignee and locating the person responsible for handling recall notifications and/or the dietary supplements involved, an opening similar to the following may be used:

This is (Name of Interviewer). I am calling for check on the effectiveness of the company recall including codes). On (date), (recalling firm) notified (how: letter, telephone, visit, mail gram, etc.) all firms which may have purchased (dietary supplements) that all stock should be (returned, destroyed, modified, relabeled, etc.). I have the following questions to ask you about this recall:

DATE _____

Did your firm receive notification that (dietary supplements name) manufactured by _____ Company are being recalled?
YES /NO

Did your firm receive shipments of the dietary supplements being recalled? (If no, terminate questioning and go to the closing).
YES /NO

Do you have any of the recalled dietary supplements on hand? (Please check inventories before answering).
YES /NO

If the answer to question 3 is YES, do you intend to return the dietary supplements to the John Doe Company as requested?
YES/NO

If the answer to question 4 is NO, please explain your intentions.
Have you received any reports of illness or injury related to this dietary supplements?
YES /NO.

If yes, please provide details.

Thank you for your cooperation.
And your name is -

Interviewer
Date

IF RESPONDENT HAS ANY FURTHER QUESTIONS, ASK HIM/HER TO CONTACT THE _____COMPANY, (PLACE), (PHONE)

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Attachment – 12
EXAMPLE OF RECALL TERMINATION LETTER

Concerned person of company
Company name
Somewhere, India

Dear Mr. _____

The Food Safety and Standard Authority of India has completed the audit of your firm's actions concerning the recall of (dietary supplements), (Code Number)(s), (Recall No.)(s). We conclude that the recall has been completed and there has been proper disposition of the recalled articles. Therefore, FSSAI considers the recall terminated.

This letter is not intended to imply that the FSSAI will not recommend civil or criminal legal action related to this matter. It does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Food Safety and Standard Regulations (or other acts as appropriate) in the future.

Sincerely,

District Director
_____ District

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Attachment – 13
EXAMPLE OF RECALL PERIODIC STATUS/FINAL REPORT

Type of product recall report: Periodic status report ☐ Final ☐

1. Product & dispatch information.

Date of dispatch	Invoice #	Export order number	Dietary Supplements	Batch #	Strength	Pack presentation	Quantity delivered

2. Description of the defect (including all reports, documents, memos, etc., of meetings, technical reviews, etc., which pertain to the analysis of the problem).
3. Consignee list (foreign and domestic) to whom the product was sold.
4. Number of consignees notified of the recall, and date and method of notification.
5. Number of consignees responding to the recall communication and quantity of dietary supplements on hand at the time it was received.
6. Number of consignees that did not respond.
7. Number of dietary supplements returned or corrected by each consignee contacted and the quantity of dietary supplements accounted for.
8. Estimated time frames for completion of the recall.
9. Number (of consignees contacted as per pre-approved effectiveness check level) and results of effectiveness checks that were made@.
10. Corrective action plan@.
    - Proposed steps to be taken to correct the dietary supplements in the field and steps taken to prevent future occurrences.
    - Proposed effectiveness checks to be conducted.
    - Proposed date of completion and appropriate interim dates for implementation of the correction.
    - Any and all injury/death investigations or reports.
    - Pertinent complaints on file.

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Attachment-14
EXAMPLE OF MOCK RECALL AUDIT REPORT

Mock Recall

AUDIT REPORT

Location :
Location code :
Purpose of audit :
Date of audit :
Audited by :
Location representative :

AUDIT FINDINGS

Physical verification of stock at Consignee against stock statement received from distribution			
Product	**Batch No.**	**Qty. as per distribution statement, as on _____**	**Qty. available at Consignee, on _____**

Product storage condition :
Product security and segregation :
Product labeling :
Remark :

Prepared by
Date

Reviewed by
Date

8. History

Version No.		**Effective Date**	