1. RECALL INFORMATION

a. RES Number: 99242 | b. Recalling Firm Name: NARA ORGANICS INC; 250 Greenwich St. Fl 39, New York, NY | c. Monitoring Division: DHFIE1

d. Product(s): Nara Organics brand Whole Milk Organic Infant Formula Milk Based Powder with Iron; 0-12 months; 24.7 oz (700G) | e. Recalled Code(s): All Lots

2. AUDIT ACCOUNTS - DIRECT ACCOUNT

a. Firm Name | b. E-mail | c. Phone No.

d. Address | e. City | f. State | g. Postal Code

SUB-ACCOUNT (SECONDARY) (*Leave blank if none.)*

h. Firm Name | i. E-mail | j. Phone No.

k. Address | l. City | m. State | n. Postal Code

SUB-ACCOUNT (TERTIARY) (*Leave blank if none.)*

o. Firm Name | p. E-mail | q. Phone No.

r. Address | s. City | t. State | u. Postal Code

3. CONSIGNEE DATA

a. Were you able to make contact?

b. Name of Person Contacted and Title | c. Method of Contact:

d. Type of Consignee (if Other, please specify in the field provided) | Other (Please Specify)

e. Does (did) Consignee receive Recalled Product? *(If Yes, answer 3f & 3g)* | f. Does (did) Consignee repackage/relabel Recalled Product or use Recalled Product to manufacture a new product? (*If Yes, detail in Remarks, and notify DRC)*

g. Did Consignee further distribute the Recalled Product to any other accounts? *(*If Yes, collect info, conduct RAC at sub-account(s) and/or provide details in "Remarks"*)*

4. NOTIFICATION DATA

a. Did the customer receive formal notification of the recall from the appropriate firm? (If answer is other than "Yes", explain in remarks and skip to 5c)

b. Recall Notification Received From ☐ Recalling Firm ☐ Direct Account ☐ Sub-Account ☐ Other *(Please Specify)*

c. Date Notification Received | d. Type of Notice Received *(e.g., letter, phone)*

5. CONSIGNEE ACTION AND RECALLED PRODUCT STATUS

a. Did the Consignee follow the recall instructions? *(If No, discuss in "Remarks" action taken as a result of audit check.)*

b. Amount (include units) of Recalled Product on hand at the time notification was Received.

c. Current Status of Recalled Products? (* = *Ensure Proper Quarantine/Action*)

d. Date of Disposition | e. Method of Disposition

f. Amount (include units) of Recalled Product **now** on hand during Recall Audit Check.

6. INJURIES/COMPLAINTS *If answer is other than "None", complete 6b and 6c, collect relevant information, document findings, and route per division procedures*

a. Is the Consignee aware of any injuries, illness or complaints?

b. Was information on how to file a complaint with FDA provided to the Consignee? *(If No, provide a reason in the remarks.)*

c. Was the complaint related to a lot code, date, etc. outside of the recall? *(If Yes, provide additional lots in the remarks.)*

7. REMARKS

(Include action taken if product was still available for sale or use.)

AUDIT CHECK

Date of Audit Check | FDA Division | Printed Name and Title | Signature

FDA ENDORSEMENT *If No, is checked for 4a and/or 5a, "Effective" cannot be selected as an Endorsement.*

Select Endorsement Type (*If Other, please specify*) | Other (*Please Specify)*

Date of Endorsement | Printed Name and Title | Signature

FDA 3177 Instruction Sheet

1. RECALL INFORMATION

a. RES Number - Enter the Recall Enterprise System (RES) number as listed in your assignment.
b. Recalling Firm Name - Provide the recalling firm name listed in your assignment.
c. Monitoring Division - Enter the monitoring division that requested the RAC assignment. Note: New recall division names are followed by the corresponding IB division names to aide in the selection.
d. Product(s) - Provide the name of the recalled product as indicated in your assignment. If numerous products are involved, use a generic term (e.g. numerous ice cream products, infusion pumps).
e. Recalled Code(s) - Provide the lot, batch, or serial number indicated as the recalled product in your assignment, or "numerous lot codes" if there are too many to list.

2. AUDIT ACCOUNTS

DIRECT ACCOUNT
a-g - Enter the Firm Name and contact information of the account that is indicated as receiving the product directly from the recalling establishment. This may or may not be the same account at which you are conducting your audit check.
SUB-ACCOUNT (SECONDARY)
h-n - If the Direct account indicates the recalled product(s) were further distributed, enter the Firm Name and contact information for the sub-account audited as well as the Direct Account section. Do not add N/A to any fields.
SUB-ACCOUNT (TERTIARY)
o-u - If the Secondary account indicates the recalled product(s) were further distributed, enter the Firm Name and contact information for the tertiary sub-account audited as well as the Direct Account and Sub-Account (Secondary) section. Do not add N/A to any fields. For quaternary and further accounts, enter the account you are auditing as a Sub-Account (Tertiary), then include the preceding accounts names in the remarks section.

3. CONSIGNEE DATA

a. Were you able to make contact? - If you have trouble making contact, three attempts should be made. If this is the case, or if the account is OOB, skip to the remarks section and explain your attempts. Choose the corresponding endorsement.
b. Name of Person Contacted and Title - The name and title of the person at the account being audited who provided the most information during the audit check.
c. Method of Contact - Choose the method used to conduct the audit check.
d. Type of Consignee - Choose the type of establishment at which you are conducting your audit check.
e. Does (did) Consignee receive Recalled Product - Choose yes or no. If the person you are talking to is unsure, select unknown. If yes, complete questions f and g.
f. Does (did) Consignee repackage/relabel Recalled Product or use Recalled Product to manufacture a new product - Select yes or no. If Yes, enter details in Remarks, collect relevant information including labeling for evaluation, and send all information to your DRC).
g. Did Consignee further distribute the Recalled Product to any other accounts - Select yes or no. If yes, carry out the audit checks to the depth indicated in the assignment. Collect the distribution list for the recalled product, the sub-recall notification, and any other pertinent information to attach to your FDA 3177. If the account has not conducted a sub-recall, then inquire with the consignee about their willingness to continue the recall to the depth specified in the recall strategy and gather as much distribution information as possible. Detail in remarks.

4. NOTIFICATION DATA

a. Did the customer receive formal notification of the recall from the appropriate firm - Indicate if the account received formal notification of the recall (check the appropriate box). Formal notification may be received from the recalling firm, direct account or the secondary/tertiary firm. If notification is received informally (e.g. press release, subscription service, or social media), indicate "No" and explain in Remarks how the account received notification. If there is some reason why you cannot determine if a notification was received (for example, it may have been discarded) indicate "Cannot be determined" and explain in Remarks.
b. Recall Notification Received From - If 4a is yes, choose the firm that formally notified the account.
c. Date Notification Received - If 4a is yes, choose the first date the account received recall notification.
d. Type of Notice Received - How the formal notification was received (letter, phone, e-mail, automated messaging system, etc.).

5. CONSIGNEE ACTION AND RECALLED PRODUCT STATUS

a. Did the Consignee follow the recall instructions - If the consignee followed or is following all of the recall instructions prior to your audit check, choose "Yes". If the consignee did not follow or has not begun to follow the recall instructions prior to your audit check, choose "No". Explain what was/was not done to date, and if the consignee took action as a result of your audit check, in the Remarks section. If the consignee is not sure if action was taken, choose "UNK".
b. Amount (include units) of Recalled Product on hand at the time of notification - The amount of recalled product the consignee had at the time they received formal notification.
c. Current Status of Recalled Products - Choose the status of the recalled items at the account at the time of your audit check. If the recalled product is still being held for sale/use, or was being held for return/correction, ensure that the account properly quarantined the product (if applicable) and followed the recall instructions. In the case of a medical device recall with instructions that permit the device to remain in use awaiting correction or servicing of the device, choose "Was Still Held for Sale/Use". Include details of the product status in the Remarks.
d. Date of Disposition - Enter the date the product was destroyed, corrected, etc. if applicable.
e. Method of Disposition - Enter specifics about the method of disposition completed or planned.
f. Amount (include units) of Recalled Product **now** on hand during Recall Audit Check - Enter how much product is on hand while you are conducting your RAC.

6. INJURIES/COMPLAINTS

a. Is the Consignee aware of any injuries, illness or complaints - Select the appropriate choice. If the answer is "None", skip 6b and 6c. If answer is other than "None", continue to 6b and 6c.
b-c. Determine if the complaint was related to the specific recalled product and codes. If the complaint is related to the specific recalled product, no additional action is necessary. If the complaint is related to a product or code not included in the recall, inform the firm about Report a Problem to the FDA, and collect relevant information, document findings, and route per division procedures. Answer 6b and 6c as appropriate.

7. REMARKS

Use this section to provide details that could not be addressed in the previous sections, or to give additional information. If you need additional space for remarks or other information, attach a written document to the 3177 and reference the attachment in the remarks section. Note: In order for 3177 results to be seen in RES, the form will populate some other field results into the remarks section automatically. Please ignore this functionality.

AUDIT CHECK and ENDORSEMENT

Complete each field accordingly. If No, Cannot Be Determined, or Unknown is checked for 4a and/or 5a, then "Effective" cannot be selected as an Endorsement.