Completing the FDA 3177 Recall Audit Check Report Form

Note: Obtain as much information as possible in order to successfully complete the FDA 3177 Recall Audit Check Report Form as follows:

1. RECALL INFORMATION

a. RES/RECALL NUMBER(S) – Enter the recall number and Recall Enterprise System (RES) number as listed in your assignment. If more than one recall number is involved, enter the lead number. In some cases, a recall number may not have been assigned yet. In these cases, 000 or 0000 will be entered as the recall number (for example, a medical device recall that does not yet have a recall number assigned, will be listed here as "Z-0000-20XX" where "XX" is the fiscal year).
b. RECALLING FIRM – Provide the name and address of the firm listed in your assignment as the recalling firm.
c. RECALLED CODE(S) – Provide the lot, batch, or serial number indicated as the recalled product in your assignment. If there are more numbers than can fit in the space, state that there are numerous lots under recall and refer to the assignment.
d. PRODUCT(S) – Provide the name of the recalled product as indicated in your assignment. If numerous products are involved, use a generic term (such as ice cream, dried fruit, etc.).

2. PROGRAM DATA – Complete as per District policy.
a. MONITORING DISTRICT – Monitoring district for the recall, as listed in your assignment.
b. FEI NUMBER OF RECALLING FIRM – FEI number of the recalling firm as listed in your assignment.
c. PAC CODE – PAC code given in your assignment.
d. HOURS – Hours spent preparing, conducting, and completing the FDA 3177 for the audit check.

3. AUDIT ACCOUNTS
a. DIRECT – The name, address, and telephone number of the account that was listed in your assignment 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.
b. SUB-ACCOUNT (SECONDARY) – If the Direct account indicates the recalled product(s) were further distributed, complete this section for each sub-account audited as well as the DIRECT account section with the name, address, and telephone number of the applicable establishments.
c. SUB-ACCOUNT (TERTIARY) – If the Secondary account indicates the recalled product(s) were further distributed, complete this section for each sub-account audited, the SUB-ACCOUNT (SECONDARY) section, and the DIRECT account section with the name, address, and telephone number of the applicable accounts.

4. CONSIGNEE DATA
Contacted by: The method used to conduct the audit check (check the appropriate box).
a. NAME OF PERSON CONTACTED & TITLE – The name and title of the person at the account being audited who provided the most information during the audit check.
b. TYPE CONSIGNEE – The type of establishment at which you are conducting your audit check (check the appropriate box – if none, check "Other" and describe the type of establishment).
c. DOES (DID) THE CONSIGNEE HANDLE RECALLED PRODUCT? – If the account at which you are conducting the audit check never received the recalled product, indicate "No". If the account received or may have received the recalled product, indicate "Yes". This includes if the company is unsure they received the recalled lot.

5. NOTIFICATION DATA
a. FORMAL RECALL NOTICE RECEIVED? – Indicate if the account received formal notification of the recall (check the appropriate box). Formal notification may be received from the recalling firm, 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 – The firm that formally notified the account at which you are conducting your audit check (check the appropriate box).
c. DATE NOTIFICATION RECEIVED – Date the account received the formal notification.
d. TYPE OF NOTICE RECEIVED – How the formal notification was received (letter, phone, e-mail, automated messaging system, etc.).

6. ACTION AND STATUS DATA
a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? – If the account followed or is following all of the recall instructions prior to your audit check, indicate "Yes". If the account did not follow or has not begun to follow the recall instructions prior to your audit check, indicate "No". Explain what was/was not done in Remarks, and if the account took action as a result of your audit check.
b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION – The amount of recalled product the account had at the time they received formal notification from the notifying firm.
c. CURRENT STATUS OF RECALLED ITEMS – Indicate the status of the recalled items at the account at the time of your audit check (check the appropriate box). 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. Include details in the Remarks
d. DATE AND METHOD OF DISPOSITION – Indicate the date and method the recalled product was destroyed/returned/corrected.

7. SUB-RECALL NEEDED? – If during the course of an audit check, you find the recalled product has been further distributed, and your audit check for the recall has not reached the depth indicated in your assignment, a sub-recall may be needed. For example, if your assignment indicates the recall depth is at the retail level, and you are auditing a wholesaler, the wholesaler should conduct a sub-recall to reach the retail level. In the case of a sub-recall, collect distribution of the recalled product, the sub-recall notification, and any other pertinent information to attach to your form FDA 3177. Carry out the recall audit check to the depth indicated in the assignment.Determine if the consignee followed the instructions and conducted a sub-recall. If they did not, 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. Indicate "Yes" in this section and add as much detail as possible in Remarks.
In some cases, if the consignee has re-labeled, repackaged, or remanufactured the recalled product, a new recall may be needed instead of a sub-recall. However, a new recall may not be needed, if the consignee has manipulated the recalled product in a way that corrects the initial reason for the recall (e.g. if the consignee re-labels the product so the labeling issue is no longer a concern, or if the consignee heat treats the product adequately to eliminate the hazard causing the original recall). If you determine a new recall is needed, or are unsure, collect all relevant information, including labeling to be evaluated with the assistance of your district's Recall Coordinator (refer to section 7.3.2.4 for labeling instructions of attachments).

Indicate "No" in this section if the product has not been further distributed and your evaluation finds that a sub-recall is not necessary.

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND – The amount of recalled product still at the account during your audit check.

9. INJURIES/COMPLAINTS
a. IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS? – Ask the consignee if they have firsthand knowledge of any injuries, illness, or complaints pertaining to the recalled product. Collect

relevant information and route per district procedures.

10. 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, use a continuation page.

CHECK – Place a handwritten or electronic signature, followed by your name and title printed or typed, the date your audit check completed, and your district.
ENDORSEMENT – Follow section 7.3.2.6 Endorsing the Audit Check. If changes need to be made after the document has been signed, the signer needs to clear the electronic signatures by right clicking on the signature and pressing “clear signature”. Then the form can be modified and re-signed.