Sections included in this document

1. Purpose

This Field Management Directive (FMD) provides guidance and criteria to Districts and Laboratories for the timely release of analytical results to the owner, operator, or agent in charge of the establishment from which certain samples (as defined in the Scope) are collected.

While this FMD addresses specific obligations the Agency has adopted, there are additional instances where communication of sample results, though not required, may be warranted. Notification of analytical results on any product may be sent to any firm, individual or cooperating agency that, in the judgment of the responsible region, has a legitimate interest in the results and when a useful purpose will be served. For more information on these procedures, refer to the ORA Laboratory Procedure, ORA-LAB.5.10, Reporting Laboratory Data.

2. Scope

This FMD applies to the following types of samples:

A. Samples of food collected during the course of an inspection of an establishment where food is manufactured, processed, or packed collected subject to section 704(d) of the Federal Food, Drug, and Cosmetic Act.

B. Samples of food including raw materials, in-process samples, and finished products where the collection establishment or dealer is voluntarily holding product pending receipt of analytical results (Dealer Voluntary Hold).

C. Environmental samples collected at an establishment where food is manufactured, processed, or packed.

3.Responsibility

A. Laboratories

1. Prepare and send “Report of Sample Analysis” (FORM FDA 1551) to the Dealer named in Collection Remarks on the sample Collection Report for all 704(d), Dealer Voluntary Hold and Environmental samples. A copy of the Form FDA 1551 letter will also be forwarded with the analytical package to the home District as identified on the CR as “Original CR & Records To” district.
2. When required per the procedures identified below, communicate sample results to the home districts’ Compliance Branch via the established email address within 24 hours of completing sample analysis and in advance of sending the FDA Form 1551, Report of Sample Analysis, to the collection or dealer firms.
3. Reconcile any concerns regarding communication of sample results to dealers/firms with the home district.

B. Districts

1. When required (as prescribed in this procedure Section 6.2; B-3), communicate analytical results directly with collection or dealer firms in advance of distribution of the FDA Form 1551, Report of Sample Analysis.

C. Sample Collectors

1. Follow the instructions in this FMD (and associated IOM references) for the Sample Flag, Sample Collection Basis and Collection Remarks sections of the FACTS Sample Collection Report.

4. Background

FDA endeavors to provide results from analytical testing of food and environmental samples without requiring the firm to submit a request under the Freedom of Information Act (FOIA) in several specific instances:

A. 704(d) Samples

Section 704(d) of the Federal Food, Drug, and Cosmetic Act requires that whenever in the course of an inspection of an establishment where food is manufactured, processed, or packed, a sample of food is obtained, and analyzed for the purpose of determining whether such food consists in whole or part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results shall be furnished promptly to the owner, operator, or agent in charge. "Unfit for food" has been used to describe foods that have an abnormal odor, abnormal color, are contained in abnormal containers (swollen cans), contaminated with pathogens, contains an undeclared allergen, etc. It has also been used for fish infested with copepods or other parasites. Any food product that may be rejected by the consumer may also be considered unfit for food. These laboratory results are reported to the firm even though the investigator may have already provided the results of the field examination on form FDA-483 (Inspectional Observations). The firm will also be notified in the event no analysis is to be performed (Lab Class V).

B. Dealer Voluntary Hold

When samples of food (including raw materials, in-process and finished products) are collected during an inspection of a food manufacturer, processor or packer, the FDA investigator will determine the manufacturer's intent with respect to holding or distributing products associated with the collected samples while FDA performs analytical testing. FDA desires to promptly provide analytical results to those firms holding products pending FDA results without requiring the firm to submit a request under the Freedom of Information Act (FOIA). Providing analytical results in this manner will allow the firm to take appropriate action. The firm will also be notified in the event no analysis is to be performed (Lab Class V).

C. Environmental Samples

FDA has determined that analytical results of environmental samples collected in food manufacturing establishments for microbiological analysis should be promptly conveyed to the firm inspected without requiring the firm to submit a request under the Freedom of Information Act (FOIA). Providing analytical results in this manner will allow the firm to take appropriate action. The firm will also be notified in the event no analysis is to be performed (Lab Class V).

5. References

IOM Sections:
4.4.10.3.64 – 704(d) Samples
4.4.10.1.5 – Factory Food Sample
4.1.1.4 – Report of Analysis
4.1.6 – Investigational Samples
4.3.7.7 – Environmental Samples

6. Procedure

6.1 Establishment of District Email Addresses for Receipt of Sample Results

A. Each District shall establish an email address entitled “ORA <District> Sample Results” and shall establish a local work instruction for membership and responsibility over monitoring email sent to that address.

B. Laboratories shall use the “ORA <District> Sample Results” email address to communicate the results of sample analysis and the decision not to analyze, pursuant to this FMD.

6.2 Communication of Sample Analysis Results

A. 704(d) Samples

1. Sample Collector: Check the 704(d) box on the FACTS Sample Collection Report and record the following in the “Collection Remarks” field: the name, title, email address and telephone/fax number of the responsible person who should receive the report of sample analysis.
2. Laboratory:

a. Complete Form FDA 1551 upon completion of testing. Under "Reason for Submission of Report", check the 704(d) box.

b. Prior to sending the FDA 1551 to the Firm/Dealer named in the collection remarks, communicate results to the home district via the established email address within 24 hours for all potentially violative results (Lab Class 3) and for those samples where no analysis was performed (Lab Class V). Include the FACTS sample number, the product and the analysis classification. Do not communicate the results for Class 1, 2, or 4 samples to the collecting district via the email process as the FDA Form 1551 will be included in the final analytical package which is sent to the home district. Include a copy of the Form FDA 1551 with the analytical package sent to the home District.

c. Send FDA Form 1551 to the Firm/Dealer named in the collection remarks on the sample Collection Report within 2 working days of the laboratory management's completion of the Sample Summary or FDA-465.

d. Send the final analytical package to the home district and include a copy of the Form FDA 1551.

3. District: As soon as sample results are provided by the analyzing laboratory, contact the responsible person at the firm/dealer holding the product and inform them on the results, or of the decision not to analyze.

B. Dealer Voluntary Hold

1. Sample Collector: As soon as the CR is created, apply the "Dealer Voluntarily Holding" sample flag to the FACTS Sample Collection Report and indicate the time period the products will be held in the sample flag remarks section. Include the following in the collection remarks: name, title, email address and telephone/fax number of the responsible person who should receive the report of sample analysis. Request the firm holding the

product to notify FDA of any subsequent change in the decision to hold or distribute the product in question.

2. Laboratory:

   a. Complete Form FDA 1551 upon completion of testing. Under "Reason for Submission of Report", check the "Other" box.

   b. Prior to sending the FDA 1551 to the Firm/Dealer named in the collection remarks, communicate results to the collecting district via the established email address. Include the FACTS sample number, the product and the analysis classification.

   c. Send "Report of Sample Analysis" (FORM FDA 1551) to the Firm/Dealer named in Collection Remarks on the sample Collection Report within 2 business days working days of the laboratory management's completion of the Sample Summary or FDA-465.

   d. Send the final analytical package to the home district and include a copy of the Form FDA 1551.

3. District: As soon as sample results are provided by the analyzing laboratory, contact the responsible person at the firm/dealer holding the product and inform them on the results, or of the decision not to analyze (Lab Class V).

C. Environmental Samples

1. Sample Collector: Utilize the appropriate product code information to identify the sample as an environmental sample. (See Field Alert 39). Include the following in the Collection Remarks: name, title, email address and telephone/fax number of the responsible person who should receive the report of sample analysis.

2. Laboratory:

   a. Complete Form FDA 1551 upon completion of testing. Under "Reason for Submission of Report", check the "Other" box.

   b. Prior to sending the FDA 1551 to the Firm/Dealer named in the collection remarks, communicate results

to the collecting district via the established email address. Include the FACTS sample number, the product and the analysis classification.

c. Send "Report of Sample Analysis" (FORM FDA 1551) to the Firm/Dealer named in Collection Remarks on the sample Collection Report within 2 business days working days of the laboratory management's completion of the Sample Summary or FDA-465.

d. Send the final analytical package to the home district and include a copy of the Form FDA 1551.

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7. Glossary/Definitions

A. **704(d) Sample:** A sample of food collected during the course of an inspection of an establishment where food is manufactured, processed, or packed to determine if the food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food.

B. **Collecting District:** The district performing the sample collection activity.

C. **Completion of Sample Analysis:** The date of the laboratory management's completion of the Sample Summary or FDA-465.

D. **Environmental Sample:** A sample collected within a food processing, packing or holding environment for which is susceptible to microbial contamination for the purpose of identifying the presence of pathogenic microorganism. (See IOM 4.3.7.7)

E. **Factory Food Sample:** A sample consisting of raw materials, in-process and/or finished products to demonstrate manufacturing conditions collected during an Establishment Inspection of a food manufacturer. This includes nutritional or medicated foods, canned foods, and medicated and non-medicated feeds.

F. **Home District:** The district most likely to pursue action if required as identified on the CR as "Original CR & Records To" district.

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8. Records

A. Form FDA 1551

http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072770.pdf

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9. Supporting Documents

None

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10. Document History

Revision	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
1.0	I	3/1/2011		Operations Management
2.0	D	8/22/2014	Donald A. Bennett Quality System Manager	Ellen Morrison
2.0	R	5/20/2015	Donald A. Bennett Quality System Manager	Ellen Morrison

* - D: Draft, I: Initial, R: Revision, C: Cancel

11. Change History

Version	Change
2.0	• Title changed from "704(d) Letters" to reflect communication of sample results for a variety of sample types. • Standardized Lab use of FDA Form 1551 for communication of results. • Standardized Lab as transmitter of FDA Form 1551 to Firm/Dealer in all cases. • Standardized information Lab is to include in notification emails to districts (sample number, product and classification). • Clarified when results will be communicated to districts via established email process: o 704(d) Samples when Class 3 or Class 5. o Dealer Voluntary Hold in all cases. o Environmental Samples in all cases. • Clarified that when called for (as above), the results will be transmitted to the district BEFORE the FDA 1551 is sent to the Firm/Dealer. • Specified results to be sent to the owner, operator or agent in charge of the firm in all cases. This is an effort to standardize routing of communications and facilitate automation for future communications. • Specified collection of email address for use in transmitting analytical results from the lab to the firm. • Added timeframe for notification of results to districts under special conditions (3., A., 2.) "When required per the procedures identified below, communicate sample results to collecting districts within 24 hours of completing sample analysis and in advance of sending the FDA Form 1551, Report of Sample Analysis, to the collection or dealer firms."
1.0	New

12. Attachments

None