

10001.1REV2SmplReservesReq byFDA110690

REVISION 02 11/06/90

OPI: S&T/PPID

SAMPLE RESERVES REQUESTED BY THE FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This directive establishes policy and procedures to be followed by Technical Support laboratories (TSL) when handling, processing, storing, shipping and disposing of samples that may indicate a violation of the Federal Food, Drug and Cosmetic Act.

II. CANCELLATION

This directive cancels FSIS Directive 10,001.1, Rev.1 dated 11/29/89.

III. REASON FOR REISSUANCE

The directive has been revised to reflect organizational changes and to further clarify the authority under which sample reserves are provided to FDA. Also, the information in the attachments has been dated.

IV. REFERENCES

FSIS Directive 7355.1, dated 2/4/88.

FSIS Directive 8150.1, Rev.1, dated 4/5/90.

FSIS Directive 10,625.1, dated 2/26/86.

MPI Regulations, Sections 310.21, 312.10, 318.9, 325.19 (a), 381.78, 381.80, 381.112, 381.146, 381.189 (a).

V. FORMS AND ABBREVIATIONS

The following form and abbreviations are used in the Directive:

CAST	Calf Antibiotic Sulfonamide Test
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
LSS	Laboratory Support Staff
TSL	Technical Support Laboratories
UAR	Unidentified Analytical Response
UMI	Unidentified Microbial Inhibitor

FSIS Form 10,000-2 - Laboratory Report

VI. DEFINITIONS

A. FDA Regulatory Reserve Samples. Violative tissue reserves of FSIS samples held for the FDA in case that Agency should need them. These samples include both domestic residue monitoring and surveillance samples with

results exceeding established tolerance or action levels.

B. Technical Support Laboratories. The three Federal laboratories in Athens, GA; St. Louis, MO; and Alameda, CA; and, the two contract laboratories; Webb Technical Group in Raleigh, NC, and NDRC Laboratories, Inc., in Houston, TX.

C. FDA Regulatory Reserve Sample Log. A computer listing providing a monthly status report of regulatory reserve samples (see examples in Attachments 1-6).

VII. SCOPE

A. For the purpose of this directive, FDA regulatory reserve samples refer to those whose analytical results indicate:

1. A residue in an edible tissue exceeding the FDA or EPA tolerance or action levels;

2. Extra-label drug use (if the finding is a violation of the Federal Food, Drug, and Cosmetic Act);

3. Contamination by an industrial or environmental pollutant if above an established tolerance or action level;

4. A residue violation discovered using in-plant tests for special programs (e.g., the Calf Antibiotic Sulfonamide Test (CAST)).

B. FDA regulatory reserve samples are limited to the following domestic residue sample types:

- 01 - Monitoring, National Random
- 02 - Monitoring, National Random, Excluding QA
- 03 - Monitoring, Area Random
- 04 - Monitoring, Plant Study
- 14 - Monitoring, National Random, First Time
- 15 - Monitoring, Area Random, First Time
- 21 - Surveillance, Selective Plant
- 22 - Surveillance, Follow-Up
- 23 - Surveillance, Inspector Generated
- 32 - Surveillance, In-Plant Positive
- 38 - Surveillance, Split

C. The following are not FDA regulatory reserve samples:

1. Inedible tissues including injection sites (except for unapproved drug use);

2. Tissues that do not contain violative levels of residues (e.g., if a residue sample consists of liver, kidney, and muscle, and only the liver is in violation then the liver reserve is the only tissue forwarded to the FDA;

3. Samples whose results produce only an unidentified microbial

inhibitor (UMI) or an unidentified analytical response (UAR).

VIII. LABORATORY ACTION

A. Initial Action. If a sample result is above the established tolerance or action level, the reserve portion of the sample will be placed in a polyethylene bag (or other appropriate container) and sealed by the analyst or sample custodian.

B. Post Review of Form Entry. After supervisory review and confirmation of the data entered on the sample submission form, the reserve sample will be placed in frozen storage to maintain its integrity.

C. No Reserve Tissue. If all violative tissue is used during analysis, note this on the FSIS Form 10,000-2. Send a copy of the form to the appropriate FDA Laboratory or District Office. Mark on the form that reserve tissue is unavailable. In the tissue column of the FDA Regulatory Reserve Sample Status Report, enter N/A. If the sample represents a retained carcass or product, request guidance from the Science and Technology, Laboratory Support Staff (LSS) to determine if additional sampling for FDA is necessary. If additional tissue is necessary, the TSL will request the inspector to forward it directly to the appropriate FDA organization. The inspector will enter the form number of the analyzed sample in block 2 of FSIS Form 10,000-2, and note "replacement tissue" in block 15.

D. Storage. With the exception of CAST violations, the laboratory will store all FDA regulatory reserve samples for a period of 1 month after the month of completion of analysis. On the first working day of each month, all eligible reserves will be shipped to the FDA District Office or laboratory having jurisdiction over the producer's business address. CAST sample reserves will be forwarded upon request by an FDA District Office. If not requested within 90 days, CAST reserves will be discarded.

E. Shipping. FDA Regulatory reserve samples should be batch-shipped using express mail or overnight express courier. Each sample reserve should be clearly labeled and identified to allow matching of the reserve to the FSIS Form 10,000-2. Before shipping, contact the appropriate FDA District Office and inform them of the shipment date and courier used. Follow procedures outlined in FSIS Directives 7335.1, 8150.1, and 10,625.1 as necessary to assure sample integrity and condition during transit. A copy of the sample submission form must accompany each sample. For residues that deplete in storage, the analyst shall mark the form "Unstable Compound-Depletes in Storage." Questions concerning sample shipping should be directed to the 702(b) Program Monitor in the appropriate FDA District Office. See Attachment 7 for FDA laboratory mailing addresses.

F. Reporting. On a monthly basis, the Eastern Laboratory will send the FDA Regulatory Reserve Sample Status Report to the FDA District Office and two complete sets of the report to the LSS. Attachment 7 is a directory of FDA District Offices.

Marvin A Norcross
Deputy Administrator

Science and Technology

Attachments

- 1 - "Example", Status Report by FDA District Office and Producer State(s) for Non-CAST Samples Forwarded to Each FDA Laboratory. (See paper copy of this directive.)
- 2 - "Example", Status Report by FDA District Office and Producer State(s) for CAST Samples Forwarded to Each FDA Laboratory. (See paper copy of this directive.)
- 3 - "Example", Status Report by FDA District Office and Producer State(s) for Completed CAST Samples. (See paper copy of this directive.)
- 4 - "Example", Status Report by FDA District Office and Producer State(s) for CAST Samples On-Hold. (See paper copy of this directive.)
- 5 - "Example", Status Report by FDA District Office and Producer State(s) for Discarded CAST Samples. (See paper copy of this directive.)
- 6 - FDA Laboratories
- 7 - FDA District Offices

FSIS DIRECTIVE 10,001.1
REVISION 2
ATTACHMENT 6

FDA LABORATORIES

Laboratory Address & Code	FDA District Office & Telephone Numbers	States Serviced
FDA (2511) Sample Custodian 01890-1197	Boston FTS: None Commercial: (617) 279-1480	Connecticut Attn: Maine 109 Holton Street Massachusetts Winchester, MA New Hampshire Rhode Island Vermont
FDA (3611) Sample Custodian Delaware Ave. Buffalo, NY 14202	Buffalo FTS: 437-4462 Commercial: (716) 846-4462	New York Attn: (Buffalo Counties) 599
FDA-New York (3612) Regional Laboratory Attn: Sample Custodian 7th Floor 850 3rd Avenue	Newark FTS: 488-5389 Commercial: (609) 757-5389	New Jersey

Brooklyn, NY 11232-1593

FDA-New York Lab (3612)	Brooklyn FTS: 663-5060 only) (718) 965-5060	New York (City Commercial
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FDA (4311) Sample Custodian 1/2 Fernandez Juncos Ave Puerta de Tierra Station Old San Juan, PR 00906-5719	San Juan FTS: (809) 753-4495 Commercial: (809) 753-4495	Puerto Rico Attn: Virgin Islands STOP 8
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FDA (2411) Attn: Sample Custodian 910 Madison Ave. Baltimore, MD 21201	Baltimore FTS: 925-2564 Commercial: (804) 771-2564	Maryland Virginia West Virginia District of Columbia
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Laboratory Address & Code	FDA District Office & Telephone Numbers	States Serviced
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FDA (4211) Sample Custodian 900, U.S. Customhouse 2nd & Chestnut Streets Philadelphia, PA 19106	Philadelphia FTS: 597-7541 Commercial: (215) 597-7541	Delaware Attn: Pennsylvania Room
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FDA-Atlanta Regional Laboratory (1311) Attn: Sample Custodian North 60 8th Street, N.E. Atlanta, GA 30309	Atlanta FTS: 257-2186 Commercial: (404) 347-2186	Georgia North Carolina South Carolina
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FDA-Atlanta Lab (1311)	Nashville FTS: 852-5079 Commercial: (615) 736-5079	Tennessee Alabama
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FDA-Atlanta Lab (1311)	Orlando FTS: 821-7160 Commercial: (305) 859-8513	Florida
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FDA (1711) IITRI Attn: Sample Custodian 3441 South Federal	Chicago FTS: 955-4792 Commercial: (217) 492-4095	Illinois
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Chicago, IL 60616

FDA (3911) Custodian Central Parkway Cincinnati, OH 45202	Cincinnati FTS: 684-3505 Commercial: (513) 684-3505	Ohio Attn: Sample Kentucky 1141
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FDA (2611) Attn: Sample Custodian 1560 E. Jefferson Ave. Detroit, MI 48207	Detroit FTS: 226-6260 Commercial: (313) 226-6260	Indiana Michigan
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FDA (2711) Attn: Sample Custodian Hennepin Ave. Minneapolis, MN 55401	Minneapolis FTS: 784-4123 Commercial: (612) 334-4123	Minnesota North Dakota 240 South Dakota Wisconsin
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Laboratory Address & Code FDA (4811) Attn: Sample Custodian 3032 Bryan Street Dallas, TX 75204-6191	FDA District Office & Telephone Numbers Dallas/Houston FTS: 255-5327 Commercial: (214) 655-5310	States Serviced Arkansas Oklahoma Texas
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FDA (2211) Sample Custodian Elysian Fields Avenue New Orleans, LA 70122	New Orleans FTS: 682-6347 Commercial: (504) 589-6344	Mississippi Attn: Louisiana 4298
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FDA (2911) Attn: Sample Custodian 1009 Cherry Street Kansas City, MO 64106	Kansas City/St. Louis FTS: 758-6376 Commercial: (816) 374-5623	Iowa Kansas Missouri Nebraska
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FDA (0811) Attn: Sample Custodian P.O. Box 25089 Denver Federal Center Building 20 Denver, CO 80225-0087	Denver FTS: 776-3000 Commercial: (303) 236-3000	Colorado Utah Wyoming New Mexico
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FDA (0611) Sample Custodian West Pico Boulevard Los Angeles, CA 90015	Los Angeles FTS: 983-6325 Commercial: (818) 904-6325	California(Footnote) Attn: Arizona 1521
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Footnote: California samples from the following counties go to Los Angeles: Imperial, Los Angeles, Orange, Riverside, San Bernadino, San Diego, Santa Barbara, and Ventura. All others go to San Francisco. If county is unknown, call FDA for assistance.

FDA (0612)
Attn: Sample Custodian
50 United Nations Plaza
Federal Office Bldg. 6
San Francisco, CA 94102

San Francisco
FTS: 556-6163
Commercial:
(415) 556-6163

California(Footnote)
Hawaii
Nevada
Guam
American Samoa

Footnote: California samples from the following counties go to Los Angeles: Imperial, Los Angeles, Orange, Riverside, San Bernadino, San Diego, Santa Barbara, and Ventura. All others go to San Francisco. If county is unknown, call FDA for assistance.

FDA (5311)
Attn: Sample Custodian
909 First Avenue
Seattle, WA 98174

Seattle
FTS: 399-5319
Commercial:
(206) 442-5319

Alaska
Idaho
Oregon
Montana
Washington

FSIS DIRECTIVE 10,001.1
REVISION 2
ATTACHMENT 7

FDA DISTRICT OFFICES

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

Attn: Tissue Residue Monitor

Food & Drug Administration
Boston District Office
One Montvale Avenue
MA 02180

Attn: Tissue Residue Monitor

Food & Drug Administration
Buffalo District Office
599 Delaware Avenue
Buffalo, NY 14202

Attn: Tissue Residue Monitor

Food & Drug Administration
Philadelphia District Office
900 US Customhouse
2nd & Chestnut Streets

Food & Drug Administration
297 Plus Park Boulevard
Nashville, TN 37217

Attn: Tissue Residue Monitor

Food & Drug Administration
New Orleans District Office
4298 Elysian Fields Avenue Stoneham,
New Orleans, LA 70122

Attn: Tissue Residue Monitor

Food & Drug Administration
Orlando District Office
7200 Lake Ellenor Drive
Suite 120
Orlando, FL 32809

Attn: Tissue Residue Monitor

Food & Drug Administration
San Juan District Office
P.O. Box 5719
Puerta de Tierra Station

Philadelphia, PA 19106

Attn: Tissue Residue Monitor

Food & Drug Administration
District Office
Madison Avenue
Baltimore, MD 21201

Attn: Tissue Residue Monitor

Food & Drug Administration
Cincinnati District Office
1141 Central Parkway
Cincinnati, OH 45202-1097

Attn: Tissue Residue Monitor

FSIS DIRECTIVE 10,000.1
REVISION 2
ATTACHMENT 7

Food & Drug Administration
Newark District Office
61 Main Street
West Orange, NJ 07052

Attn: Tissue Residue Monitor

Food & Drug Administration
Atlanta District Office
60 Eighth Street Northeast
Atlanta, GA 30309

Attn: Tissue Residue Monitor

Food & Drug Administration
Denver District Office
Bldg. 20, Denver Federal Center
6th & Kipling Street
P.O. Box 25087
Denver, CO 80225-0087

Attn: Tissue Residue Monitor

Food & Drug Administration
San Francisco District Office

San Juan, PR 00906-5719

Attn: Tissue Residue Monitor

Food & Drug Administration Baltimore
Chicago District Office 900
1222 PO Building
433 W. Van Buren Street
Chicago, IL 60607

Attn: Tissue Residue Monitor

Food & Drug Administration
Detroit District Office
1560 E. Jefferson
Detroit, MI 48207

Attn: Tissue Residue Monitor

Food & Drug Administration
Minneapolis District Office
240 Hennepin Avenue
Minneapolis, MN 55401

Attn: Tissue Residue Monitor

Food & Drug Administration.
Dallas District Office
3032 Bryan Street
Dallas, TX 75204

Attn: Tissue Residue Monitor

Food & Drug Administration
Kansas City District Office
1009 Cherry Street
Kansas City, MO 64106

Attn: Tissue Residue Monitor

Food & Drug Administration
Los Angeles District Office
1521 W. Pico Boulevard
Los Angeles, CA 90015-2486

Room 526, Federal Office
50 U.N. Plaza
San Francisco, CA 94102

Attn: Tissue Residue Monitor Building

Attn: Tissue Residue Monitor

Food & Drug Administration
Seattle District Office
22201 23rd Drive Southeast
Bothell, WA 98021-4421

Attn: Tissue Residue Monitor