FDA AFFIDAVITS, REQUEST FOR SHIPPING RECORDS, RECEIPT FOR SAMPLES AND PHOTOGRAPHS

Technical Bulletin O-03

SPA periodically receives questions about Food and Drug Administration (FDA) procedures during the course of establishment inspections and investigations, including affidavits, requests for shipping records, receipt for samples and photographs. It is recommended the following information be reviewed, company policies established, all levels of management be made aware of the company policies and the policies followed during FDA inspections and investigations.

Affidavits

FDA’s regulatory jurisdiction is based upon the receiving and/or shipment of finished products, raw materials and/or packaging materials in interstate commerce. FDA may prepare and ask company personnel to sign a prepared affidavit (statement) to establish interstate commerce during an inspection or investigation, especially when a sample is collected. **There is no legal requirement to sign an affidavit or legal ramifications for refusing to sign the document.**

Affidavits are typically obtained by FDA from persons who have dealt with the goods sampled in some manner and/or events affecting their condition. Such facts, recorded in writing and signed by the person who can testify in court to those facts, can either be used to establish federal jurisdiction or assign responsibility for a violation. The statement may identify documents proving interstate shipment of the goods sampled, it may name the person who could testify to the identity of the goods sampled and/or it may certify that the goods collected are from the lot of goods covered by the shipping records obtained. The FDA inspector will prepare the statement using various affidavit forms, including Forms FDA 463a, 1664 and 1664b – see enclosed examples.

Affidavits can also be used to connect adverse conditions observed during an inspection (and subsequently listed on a Form FDA 483, Inspectional Observations) with documentation of interstate commerce. For example, the affidavit could cite the company’s failure to monitor a temperature critical limit at a critical control point --- or conflicting or falsified information in the monitoring records --- and associate the observation with the shipping records documenting interstate movement of the affected finished product, raw materials and/or packaging materials. In this manner, the signature of the affidavit by company personnel attests to the validity of the inspector’s observations on the Form FDA 483 and establishes jurisdiction which supports --- and may result in --- regulatory action by FDA.

Revision Date: 3-13-14
Supersedes: Technical Bulletin O-03, 3-23-12
If company personnel refuse to sign an affidavit, additional efforts may be made by FDA inspectors to have company personnel acknowledge the truthfulness of the affidavit by asking the company representative to:

- At least initial the affidavit after reading the document;
- Read the affidavit and verbally acknowledge the statement is true and correct (or the inspector will read the statement and ask for acknowledgement);
- Hand write a statement at the bottom reading “I have read this statement and it is true, but I am not signing it because [fill in the reason, e.g., company policy]” and sign or initial the added disclaimer; and/or
- Review and make corrections to the statement and initial each item.

Although the affidavit is not signed, these alternative approaches validate the affidavit and it may be used for pursuing regulatory action. Therefore, be advised that reading, having it read, making corrections or otherwise acknowledging the affidavit may have consequences and support regulatory action by FDA.

In the event the company’s policy is to allow signature of FDA prepared affidavits, the affidavit should be reviewed carefully to make any corrections and additions; and should be signed before the FDA inspector signs it since it is attesting to the fact that the affiant has read and understood the statement and has confirmed that the statement is the truth. Review of the affidavit by the company’s legal counsel is also recommended.

**Request for Records**

For FDA to initiate regulatory action, interstate commerce jurisdiction must be established. (Warning letters may be issued without documentation of jurisdiction.) Most often this is accomplished by documenting interstate movement of finished product, raw materials and/or packaging materials by obtaining copies of shipping records along with a signed affidavit.

**Records**

21 U.S.C §373. (Section 703 of the Federal Food, Drug and Cosmetic Act) requires that common carriers or persons receiving or holding food in interstate commerce shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of that food. The officer or employee must first explain that the law requires the records be furnished to the FDA only after a written request has been issued.

The written request must specify the nature or kind of food to which such a request relates. **Records obtained on request** under this section shall not be used in a criminal prosecution of the person from whom they are obtained. However, it should be noted that shipping records **provided voluntarily** may support regulatory action by FDA.
The Investigators Operations Manual Section 4.4.7.2.2 specifies the content of a written request for records to read as follows:

“Pursuant to Section 703 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 373) permission is hereby requested for access to and copying of all records showing quantity, shipper and consignee, showing movement in interstate commerce and/or the holding after interstate movement of ____________.”

The written request must clearly identify the lots which are the subject of the request, the firm and the individual to whom the request is given.

Records typically collected to document interstate commerce are waybills, freight bills and bills of lading. Invoices do not document interstate commerce but are usually requested to show the intent to sell the goods and establish the value of the goods sampled.

**Emergency Records Access**

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) originally provided FDA with “emergency” authority to access records regarding a food that may present a threat of serious adverse health consequences or death. The Food Safety Modernization Act (FSMA) expanded the scope of FDA’s emergency records access authority in relatively limited ways, so as to also cover records about other foods that may be affected in a similar manner.

FDA is likely to use their authority to access records related to foods in response to actions such as recalls, products reported to the reportable food register, consumer complaints, and other situations where a product presents a threat of serious adverse health consequences to humans or animals.

The types of records that may be accessed and copied by FDA under the emergency provisions include: (1) manufacturing records; (2) raw materials (ingredients and packaging) receipt records; (3) product distribution records; (4) product inventory records; (5) test records; (6) recall records; (7) reportable food records; (8) customer distribution lists; and (9) complaint and adverse event records.

The types of records that may **not** be accessed or copied by FDA under the emergency provisions include: (1) recipes for food; (2) financial data; (3) pricing data; (4) personnel data; (5) research data (except test marketing a food), or (6) sales data, other than shipment data regarding sales.

The following table summarizes the FDA accessibility requirements under both routine inspections, and under emergency access provisions that are invoked under Sections 414(a) and 704(a) of the Federal Food, Drug, and Cosmetic Act. It should also be noted that a firm may exercise their own discretion with regard to providing records for which access is not mandatory; however, we recommend these records are provided only upon receipt of a written request.
### Record(s) or Document:

<table>
<thead>
<tr>
<th>Record(s) or Document:</th>
<th>FDA Access during Routine Inspection</th>
<th>FDA Access under Emergency Access Provisions&lt;sup&gt;1, 2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shipping records documenting movement of product in interstate commerce</td>
<td>Yes&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Yes</td>
</tr>
<tr>
<td>LACF Records - visual seam exams, double seam exams, retort records</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Hazard Analysis</td>
<td>No</td>
<td>Yes, if a written Hazard Analysis exists</td>
</tr>
<tr>
<td>HACCP Plans</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>HACCP CCP Records</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sanitation Standard Operating Procedures</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Sanitation Control Procedure monitoring records (21 CFR 123.11)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Importer Verification Records (21 CFR 123.12) - Product Specifications and records related to any of the Affirmative Steps</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Weight Records</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Providing copies of product labels</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Microbiological test results on product</td>
<td>No, except when results are from tests used for HACCP verification</td>
<td>Yes</td>
</tr>
<tr>
<td>Environmental microbiological monitoring test results</td>
<td>No, except when results are from tests used for HACCP verification</td>
<td>Yes</td>
</tr>
<tr>
<td>Recall Plan</td>
<td>No</td>
<td>Yes, if a written recall plan exists</td>
</tr>
<tr>
<td>Consumer Complaint Records</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Sales Data (not related to shipping)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Recipes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Personnel Data</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Research Data</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Test Market Data</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Financial Data</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Pricing Data</td>
<td>No</td>
<td>No</td>
</tr>
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</table>

Reference: FDA Regulatory Procedures Manual - 10-4 - [INSPECTION OF FOOD RECORDS - SECTIONS 414(a) and 704(a)]

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<sup>1</sup> If FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA has authority to access and copy all records relating to such articles that are needed to assist FDA in making this determination.

<sup>2</sup> An investigator or other authorized FDA personnel, upon presentation of credentials, will issue a written notice, Form FDA 482c, to the owner, operator, or agent in charge, informing that person of the records requested and FDA's legal authority to obtain such records. FDA may request additional records related to the implicated food at a later time under the same authority.

<sup>3</sup> Records access may be provided on written request.
Companies should review the types of records FDA specifies under their broader authority as policies regarding records access are developed.

Form FDA 484, Receipt for Samples

FDA has the legal authority to collect samples under Section 704(c) of the Food, Drug and Cosmetic Act. A Form FDA 482, Notice of Inspection is not required but is usually issued upon request; requesting the form is recommended to document the presence of the inspector in the facility. When a sample is collected, a Form FDA 484, Receipt for Samples must be issued by FDA for any physical evidence removed from the facility, including raw materials, finished products, environmental swabs, and filth exhibits such as rodent pellets and insects. FDA is not required to issue a Form FDA 484 for photographs, shipping records, labels or HACCP monitoring, corrective action or verification records.

FDA will request a signature on the Form FDA 484. There is no legal ramification for signing or refusing to sign the FDA 484. A signature on the form just acknowledges whether the sample was purchased, how it was or will be paid for, or was provided to FDA at no charge. FDA routinely pays for samples and there are no ramifications for charging for samples.

Photographs

Photographs are FDA’s most effective form of evidence. FDA personnel will not ask permission before taking photographs during an inspection. They will bring their camera into the facility along with other inspectional equipment and use it unless the company clearly states their policy of no cameras in the facility. If a company has a “no camera/photography” policy, the policy should be communicated to the FDA inspector during the opening meeting and before the inspection begins. It is important to communicate to the inspector in a courteous but firm manner and that the no photograph policy is not a “refusal to inspect.”

If photographs are refused, FDA inspectors will attempt to persuade company personnel to allow photographs and may cite “Dow Chemical v. United States (1986)” and “United States of America v. Acri Wholesale Grocery Company (1976).” However, these cases do not give clear authority to FDA to take photographs. In the latter case, the court ruled in favor of the FDA because the company did not state the “no photograph policy” to the inspector until after several photographs had been taken.

If photographs are refused, the inspector will request the name and contact number of the company’s legal counsel. The information will be forwarded to headquarters who may contact the company’s legal counsel to discuss the refusal. For this reason, legal counsel should be involved in developing the policy and be prepared to support the company policy if contacted. FDA may pursue a court order to allow the use of photography but this action would only be pursued when the most egregious conditions are observed. If the company is presented with a court order allowing FDA to take photographs, the company must comply.
If photographs have been taken without the company’s approval, FDA inspectors will not
destroy or surrender the photographs taken (e.g., film, disc) since it is government property.
However, copies of all photographs may be obtained under the Freedom of Information Act.
This is why it is important to communicate the company’s “no camera/photography policy” prior
to the start of the inspection, if the company has such policy.

FDA personnel are allowed to take photographs in facilities that are signators of the Salmon
Control Plan. At the conclusion of the inspection, FDA must identify the number of exposures
taken. Also, be aware that some states agencies making contract inspections for FDA have the
authority to take photographs in their regulations, and will use that authority to take photographs.

In conclusion, company personnel should be aware of the company policies. Depending upon
the established policies, company personnel should respond to requests by simply stating,
“Company policies do not allow signing affidavits, providing shipping records without
appropriate written request and/or allowing photographs.”

Further Assistance
Please do not hesitate to contact the SPA staff below if you have any questions or require further
assistance with regulatory inspection issues.

Chris Rezendes: crezendes@spa-food.org    Kenny Lum: klum@spa-food.org
**FDA Affidavit Examples:**

**FORM FDA 463a**

<table>
<thead>
<tr>
<th>AFFIDAVIT</th>
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<tbody>
<tr>
<td>Kansas</td>
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Before me, **Sidney H. Rogers**, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 630; Reorganization Plan No. IV, Secs. 13-16, effective June 30, 1940; Reorganization Plan No. 1 of 1933, Secs. 1-4, effective April 11, 1933; and P.L. 86-88, Sec. 506, 80 Statutes at Large 865 (20 U.S.C. 3500), effective May 4, 1968; to administer or take oaths, affirmations, and affidavits, personally appeared **Joseph H. Roe** in the county and State aforesaid, who, being duly sworn, deposes and says:

I am the Vice President in charge of production of the Doe Bottling Co., Inc., 123 Main, Thistown, Kansas 67201; and as such I have knowledge of the raw material receiving and use, and carbonated beverage production at this firm.

The sample consisting of two cases, 48-10 ounce bottles, of Kola Cola, coded ABCD, collected by Investigator Rogers on November 15, 1999 was from a lot of 2668 cases produced by this firm on October 7, 1999. The copies of our production records for October 7, 1999 consist of a Syrup Room Report dated 10-6-99, a two-page Production Report dated 10-7-99, an un-dated in-line Control record, and a Finished Drink Control Record dated 10-7-99. Copies of these records were provided to the investigator and cover our production of this lot.

The above described lot was made in part from a portion of a lot of bulk liquid sugar received October 3, 1999 from the Sweet Sugar Co. Code: 1999, in railroad bulk car ATSF 98765, unloaded October 6, 1999. The copies of the Sweet Sugar Co. Invoice number 464 dated Sept. 26, 1999; freight waybill number UP-3579 dated Sept. 27, 1999 issued by the Union Pacific Railroad Co.; and our receiving report number 01-23 dated October 6, 1999 were provided to the investigator and cover this shipment.

The above described lot was also made in part from a portion of a lot of Kola Cola syrup base received September 23, 1999 from the Kola Cola Co., Thattown, Texas. The copies of Kola Cola Co. Invoice number KCO12935 dated Sept. 20, 1999; freight bill number X-98125 dated Sept. 21, 1999 issued by Speedy Truck Line Co.; and our receiving report number 01-01 dated Sept. 23, 1999 were provide to the investigator and cover this shipment.

The above described lot of Kola Cola was identified to the investigator by William S. Doe, Production Supervisor. I identified and provided copies of the records to the investigator.

**AFFIANT’S SIGNATURE AND TITLE**

Joseph H. Roe, Production Vice President

**FIRM’S NAME AND ADDRESS (Include ZIP Code)**

Doe Bottling Co., Inc. 123 Main, Thistown, Kansas, 67201

**Subscribed and sworn to before me at Thistown, Kansas this 15th day of November, 1999.**

[Signature]

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1933, effective April 11, 1933; and P.L. 86-88 effective May 4, 1968.

**FORM FDA 463a (4/83)**

**PREVIOUS EDITIONS ARE OBSOLETE**

**PAGE ** OF ** PAGES**
FORM FDA 1664

STATE OF Arkansas
COUNTY OF Jefferson

Before me, Sidney H. Rogers, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary under authority of the Act of January 31, 1925, 43 Statutes at Large 933; Reorganization Plan No. IV, Secs. 12-13, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-8, effective April 11, 1953; and P.L. 96-88, Secs. 599, 95 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980, to administer or take oaths, affirmations, and affidavits, personally appeared Henry O'Rourke, in the county and State aforesaid, who,

being duly sworn, deposes and says: The sample consisting of Two Cases (24/8 oz. Each) Horseshoe Brand Canned Cove Oysters collected by the above FDA employee on 3-10-99 was from shipment(s) received by us from Captain Sam Seafood, Inc. New Orleans, LA on 3-7-99 and so identified to the collector:

That the copy of invoice(s)

<table>
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<tr>
<th>NUMBER</th>
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<th>NUMBER</th>
<th>DATE</th>
<th>NUMBER</th>
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</thead>
<tbody>
<tr>
<td>1)</td>
<td>06641</td>
<td>3/6/99</td>
<td>2)</td>
<td>06643</td>
</tr>
</tbody>
</table>

and (copy of shipping record(s):)

<table>
<thead>
<tr>
<th>TYPE &amp; NUMBER</th>
<th>DATE</th>
<th>Issuing Firm or Carrier</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) F/B 4778</td>
<td>3/6/99</td>
<td>Acme Freight Lines, Inc. MOLA</td>
</tr>
</tbody>
</table>

which were identified and furnished the collector, cover this case shipment(s):

That said shipment(s) was (were) entered for the account of

under Lot no. 8

The collector paid me the sum of $21.32 (in cash) (by check (to be billed) for the sample.

REMARKS

AFFIDAVIT SIGNATURE & TITLE

Henry O'Rourke, Warehouse Manager Plant #12
Southeastern Seafood Distributors, Inc.
#4 Canal Street Dock Red River Basin Area, Little Rock, AR 72901

Subscribed and sworn to before me at Little Rock, AR

this 10th day of March, 1999

(Signed) Sidney H. Rogers

cont. FDA Affidavits, Request for Records, Receipt for Samples and Photographs

FORM FDA 1664a

<table>
<thead>
<tr>
<th>STATE OF</th>
<th>COUNTY OF</th>
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<tbody>
<tr>
<td>Arkansas</td>
<td>Jefferson</td>
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</table>

Before me, ___________ Sylvia A. Rogers ___________, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary under authority of the Act of January 31, 1925, 43 Statutes at Large 805; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 309, 93 Statutes at Large 865 (20 U.S.C. 3508), effective May 4, 1980, to administer or take oaths, affirmations, and affidavits, personally appeared ___________ Patrick T. Palmer ___________, in the county and State aforesaid, who, being duly sworn, deposes and says: The lot of ___________ The lot of 325 cases, (24/ 4 1/2 oz. cans) of Jolly Miller Canned Mushrooms

which we invoiced and sold to ___________ Patriot Markets, Inc. Frankford, Pennsylvania ___________ on ___________ 4-12-99 ___________.

was a portion/all of a parcel shipped to us by ___________ Northern Light Foods, Inc. Duluth, Minnesota ___________.

and is covered by submitted (copy of) invoice(s):

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
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</thead>
<tbody>
<tr>
<td>3914</td>
<td>4/4/99</td>
</tr>
</tbody>
</table>

and (copy of) shipping record(s):

<table>
<thead>
<tr>
<th>TYPE</th>
<th>NUMBER</th>
<th>DATE</th>
<th>ISSUING FIRM OR CARRIER</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) B/L</td>
<td>20018</td>
<td>4/5/99</td>
<td>Northern Freight Carriers</td>
</tr>
<tr>
<td>2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

___________ Patrick T. Palmer ___________, Warehouse Manager Plant #12

Firm (Name and address, include ZIP Code)

Liberty Wholesale Grocers
3210 11th Ave. Frankford, PA 19105

Subscribed and sworn to before me at ___________ Frankford, PA ___________ this ___________ 28th ___________ day of ___________ April ___________ , 1999

___________ Sylvia A. Rogers ___________

(Declarant's Signature)


FORM FDA 1664a (4/83) PREVIOUS EDITIONS ARE OBSOLETE