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Sections included in this document

1. Purpose
2. Scope
3. Guidelines
4. Procedure/Responsibilities
5. Background
6. Reference/Supporting Documents
7. Definitions/Glossary
8. Records
9. Attachments
10. Document and Change History

1. Purpose

This Field Management Directive (FMD) provides guidance and criteria for implementing Memorandum of Understanding (MOU) Number 225-09-0008 between the United States Department of Health and Human Services Food and Drug Administration (FDA) and the United States Department of Commerce National Oceanic and Atmospheric Administration (NOAA) that provides for cooperation and information sharing in the inspection of fish and fishery products and establishments. (see 5. Reference/Supporting Documents C)

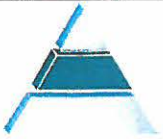
The MOU sets forth the working arrangements between the two agencies to facilitate each agency's efforts to discharge its responsibilities related to the inspection of fish and fishery products.

This FMD describes the steps that will be taken and assigns responsibility for each step to ensure that cooperation and information sharing relative to the inspection of fish and fishery products is executed as defined in the MOU.

2. Scope

This FMD becomes effective upon issuance and applies to FDA inspections of National Marine Fisheries Services (NMFS) *Approved Establishments* and FDA advisory and regulatory actions that have been recommended or executed against fish and fishery products or the establishments that handle fish and fisheries products for which FDA has jurisdiction.

More specifically, this FMD encompasses both domestic and international inspections of NMFS *Approved Establishments* performed by FDA or by any state/local authorities under contract with FDA. It applies to FDA warning letters issued against seafood establishments or the fish or fishery products associated with these establishments and regulatory actions (seizure, injunction, administrative detention, suspension of registration, mandatory recalls) either taken

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or intended to be taken against fish or fishery products in such establishments or the establishment itself.


3. Guidelines

A list of NMFS *Approved Establishments* [those processing establishments or vessels that have voluntarily contracted with NMFS for inspection services and have been sanitarily inspected, approved, and certified by NMFS as being capable of producing safe, wholesome products in accordance with specific quality regulations promulgated by the U.S. Department of Commerce] and NMFS Seafood Inspection Program Offices, including contact information, can be found in the "USDC Participants List of Firms, Facilities and Products," available at: <http://www.seafood.nmfs.noaa.gov/>.

4. Procedure/Responsibilities

A. **The Investigator** conducting inspections of fish and fishery product establishments will:

1. Determine whether the processing plant is a NMFS *Approved Establishment* prior to initiating an inspection by accessing the list of such firms at <http://www.seafood.nmfs.noaa.gov/>. If the plant is a NMFS *Approved Establishment*:
 - a) Invite the NMFS inspector assigned to and present in the processing plant to accompany you during your inspection. If you learn after initiating your inspection that the firm is a NMFS *Approved Establishment* but perhaps had not yet been included as part of the published NMFS *Approved Establishment* list, contact the assigned NMFS inspector and apprise them of your inspection. Invite the NMFS inspector to participate in the inspection, if available, and if the inspection is still in progress.
 - b) Offer to verbally share inspection observations with the NMFS inspector assigned to and present in the processing plant at the conclusion of the inspection and prior to the discussion with plant management. This offer should be made to NMFS inspectors that accompany you during the inspection and those that choose not to or were unable to participate in the FDA inspection. Do not disclose trade secret, commercial confidential information.
 - c) Provide a copy of Inspectional Observations (FDA 483), redacted if necessary, to the NMFS inspector assigned to and present in the processing plant at the conclusion of the inspection, after the discussion with plant management. If the FDA 483 contains trade secret, commercial confidential information and requires redaction prior to sharing, advise the NMFS inspector of this fact and inform the inspector that a redacted copy of the FDA 483, when available, will be provided to the appropriate NMFS field office by FDA District management
 - d) Notify, your supervisor, who will inform the Director of Investigations Branch if a copy of Inspectional Observations (FDA 483) was not provided to the NMFS inspector at the conclusion of the inspection.

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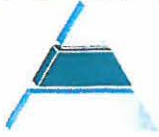
- e) Document the following information in all EIRs that pertain to NMFS *Approved Establishments*: the name of the NMFS inspector and whether the NMFS inspector was on the premises during the FDA inspection; whether or not the NMFS inspector accompanied you during the inspection or declined to participate; that the inspectional observations were verbally shared with the NMFS inspector; and whether or not a copy of the FDA 483 was provided to the NMFS inspector.
2. Notify your supervisor, who will notify the Director of Investigations Branch and the District Director, if you are asked to testify in a case in which NMFS is a party.
3. Decline to testify for a private entity in a case in which NMFS is a party unless that entity has complied with FDA's "Touhy" regulations, including issuance of a subpoena. FDA's "Touhy" regulations can be found in Title 21 of the Code of Federal Regulations (CFR) §§ 20.1 and 20.2 [21 CFR 20.1 and 20.2].

B. The Director of the Investigations Branch in each district will:

1. Maintain close working relations with key personnel in appropriate NMFS field office(s) and meet periodically, as resources permit, for purposes of program planning, coordination, evaluation, and review concerning inspectional matters of mutual interest and to serve as a clearinghouse for questions and problems as they arise.
2. Provide a copy of Inspectional Observations (FDA 483); redacted as appropriate, for a NMFS *Approved Establishment* to the appropriate NMFS field office if the Investigator did not provide a copy to the NMFS inspector at the conclusion of an inspection.

C. The Director of the Compliance Branch in each district will:

1. Notify the Director of the Seafood Inspection Program (NMFS Headquarters), in writing, when FDA has sent a Warning Letter to a fish or fishery product establishment in the district (See Appendix A). The notification should include a redacted copy of the Warning Letter. A copy of this notification should be sent to the Chief Quality Officer of the Seafood Inspection Program (NMFS Headquarters) and the Director of the Division of Seafood Safety (DSS) in the Center for Food Safety and Applied Nutrition (CFSAN) Office of Food Safety (OFS) (HFS-315).
2. Notify the Director of the Seafood Inspection Program (NMFS Headquarters), in writing, when the District, after consultation with the appropriate Center and OCC, is preparing a case recommendation for a regulatory action (e.g., seizure, or injunction) against a fish or fishery product or establishment in the district and again when such action has been executed, i.e., the complaint has been filed; the seizure action executed. For seizure actions - See Appendix D and E) (For injunctions - See Appendix B and C). Also notify the Director of the Seafood Inspection Program

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(NMFS Headquarters) when the Agency has utilized the following authorities against a fish or fishery establishment or the fish and fishery products handled by such an establishment: administrative detention, suspension of registration, or mandatory recall (see Appendix C and E). A copy of this notification should be sent to the Chief Quality Officer of the Seafood Inspection Program (NMFS Headquarters) and the Director of the Division of Seafood Safety (DSS) in the Center for Food Safety and Applied Nutrition (CFSAN) Office of Food Safety (OFS) (HFS-315).

D. The District Director in each district will:

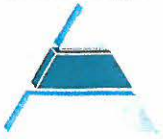
1. Maintain close working relations with Chief of the appropriate NMFS Regional Inspection Branch(s) and meet periodically, as resources permit, for purposes of program planning, coordination, evaluation, and review concerning inspectional matters of mutual interest and to serve as a clearinghouse for questions and problems as they arise.
2. Notify the Director of Seafood Inspection Program (NMFS Headquarters), in writing, when an employee or FDA inspector has been asked to testify in a case in which NMFS is a party (See Appendix F). A copy of this notification should be sent to the Chief Quality Officer of the Seafood Inspection Program (NMFS Headquarters) and to the Director of the Division of Seafood Safety (DSS) in the Center for Food Safety and Applied Nutrition (CFSAN) Office of Food Safety (OFS) (HFS-315).

E. The Director of the Office of Regional Operations or designee in ORA Headquarters will:

Maintain close working relations with Director of the Seafood Inspection Program (NMFS Headquarters), and meet periodically, as resources permit, for purposes of program planning, coordination, evaluation, and review concerning inspectional matters of mutual interest and to serve as a clearinghouse for questions and problems as may arise.

F. The Director of the Division of Human Resource Development or designee in ORA Headquarters will:

1. Make relevant formal training courses available to the NMFS personnel, as resources permit.
2. Send a written invitation to the Training Services contact in the Technical Services Branch of the Seafood Inspection Program (NMFS Headquarters), inviting NMFS personnel to attend FDA/ORA education/training or certification related activities. A copy of this invitation will be sent to the Director of the Seafood Inspection Program (NMFS Headquarters) and to the Director of the Division of

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Seafood Safety (DSS) in the Center for Food Safety and Applied Nutrition (CFSAN)
 Office of Food Safety (OFS) (HFS-315)(see Appendix G).

5. Background – N/A

6. References/Supporting Documents

- A. FDA Investigations Operations Manual:
 - a) Chapter 1 – Administration, Subchapter 1.4 – Disclosure of Official Information
 - b) Chapter 3 - Federal and State Cooperation, Subchapter 3.1 Cooperative Efforts, Subchapter 3.2 - Federal Agency Interaction, 3.2.2 - U.S. Department of Commerce (DOC), 3.2.2.2 - National Oceanic and Atmospheric Administration (NOAA) - National Marine Fisheries Service (NMFS)
 - c) Chapter 5 - Establishment Inspections, Subchapter 5.4 - Food, 5.4.9 - Other Government Inspection, 5.4.9.1 - Federal
- B. FDA Regulatory Procedures Manual, Chapter 3 - Commissioning and Work Sharing, 3-6 - Confidentiality, 3-6-5 - Sharing Non-public Information under 21 C.F.R. § 20.85 (Federal).
- C. MOU Number 225-09-0008 signed October 9, 2009



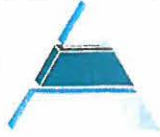
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7. Definitions/Glossary – N/A

8. Records – N/A

9. Attachments



- Appendix A:** MODEL NOTIFICATION LETTER - Warning Letter to a Fish or Fishery Product Establishment.
- Appendix B:** MODEL NOTIFICATION LETTER – Regulatory Action against a Fish or Fishery Product Establishment (case recommendation - injunction).
- Appendix C:** MODEL NOTIFICATION LETTER - Regulatory Action against a Fish or Fishery Product Establishment (actual – injunction, suspension of registration).
- Appendix D:** MODEL NOTIFICATION LETTER – Regulatory Action against a Fish or Fishery Product(s) (case recommendation - seizure).
- Appendix E:** MODEL NOTIFICATION LETTER – Regulatory Action against a Fish or Fishery Product(s) (actual – seizure, administrative detention, mandatory recall).

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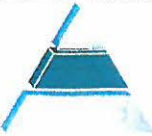
Appendix F: MODEL NOTIFICATION LETTER – Employee or FDA inspector has been asked to Testify in a case in which NMFS is a party.

Appendix G: MODEL INVITATION LETTER – FDA’s Office of Regulatory Affairs (ORA) Investigator Certification Program and related activities.

10. FMD Document History/Change History

Version #	Status* (D, I, R, C)	Date	Author Name and Title	Approving Official Name and Title
1.0	INITIAL	10/31/11	 QUALITY SYSTEM MANAGER	 Deputy Associate Commissioner for Regulatory Affairs - Field Operations

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

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Appendix A: MODEL NOTIFICATION LETTER - Warning Letter to a Fish or Fishery Product Establishment.

(Appropriate Letterhead)

FOR OFFICIAL USE ONLY

[Date]

[Director's Full Name], Director
 Seafood Inspection Program
 USDC, NOAA, NMFS
 1315 East-West Highway
 Silver Spring, MD 20910

Dear [Title] [Director's Last Name]:

This letter is in reference to the signed Memorandum of Understanding (MOU) between U.S. Department of Commerce, National Oceanic and Atmospheric Administration, and U.S. Department of Health and Human Services, Food and Drug Administration (FDA), dated October 9, 2009, for cooperation and information sharing in the inspection of fish and fishery products and establishments (MOU Number 225-09-0008).

In accordance with section 3.B.3 of the MOU, FDA is informing you that a Warning Letter (attached) has been sent to the firm listed below:

[Firm Name and Address] (FDA FEI # [Firm FEI number])

This non-public information is provided for official use only and may constitute or contain non-public privileged or confidential information which is exempt from public disclosure under 5 U.S.C. Section 552, 18 U.S.C. section 1905, or other applicable statutes.

Access to this non-public information is restricted to authorized FDA and National Marine Fisheries Service (NMFS) employees, agents, and officials who require access to perform their official duties in accordance with the uses of the information as authorized in the MOU, unless authorized in writing by FDA or otherwise required by law.

Please feel free to contact our office with any questions.

Sincerely,
 [Sender's Full Name]
 [Sender's Title]
 [Sender's Office]

Attachment: Warning Letter (FDA FEI # [Firm FEI number])

cc: [Chief Quality Officer's Full Name], Chief Quality Officer
 Seafood Inspection Program
 USDC, NOAA, NMFS
 1315 East-West Highway
 Silver Spring, MD 20910
 [Director's Full Name], Director
 Division of Seafood Safety (HFS-315)
 FDA, Office of Food Safety
 5100 Paint Branch Parkway
 College Park, MD 20740

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10/31/2011**Appendix B: MODEL NOTIFICATION LETTER – Regulatory Action
against a Fish or Fishery Product Establishment (case recommendation)**
(Appropriate Letterhead)

FOR OFFICIAL USE ONLY

[Date]

[Director's Full Name], Director
Seafood Inspection Program
USDC, NOAA, NMFS
1315 East-West Highway
Silver Spring, MD 20910

Dear [Title] [Director's Last Name]:

This letter is in reference to the signed Memorandum of Understanding (MOU) between U.S. Department of Commerce, National Oceanic and Atmospheric Administration, and U.S. Department of Health and Human Services, Food and Drug Administration (FDA), dated October 9, 2009, for cooperation and information sharing in the inspection of fish and fishery products and establishments (MOU Number 225-09-0008).

In accordance with section 3.B.3 of the MOU, FDA is informing you that we intend to take a [injunction.] action against firm and/or the operator(s) of the firm listed below:

[Firm Name and Address] (FDA FEI # [Firm FEI number])

Please note that FDA has not made a final decision on this regulatory action. We will inform your office when a final decision is made on this matter.

This non-public information is provided for official use only and may constitute or contain non-public privileged or confidential information which is exempt from public disclosure under 5 U.S.C. Section 552, 18 U.S.C. section 1905, or other applicable statutes.

Access to this non-public information is restricted to authorized FDA and National Marine Fisheries Service (NMFS) employees, agents, and officials who require access to perform their official duties in accordance with the uses of the information as authorized in the MOU, unless authorized in writing by FDA or otherwise required by law.

Please feel free to contact our office with any questions.


Sincerely,

[Sender's Full Name]

[Sender's Title]

[Sender's Office]

cc: [Chief Quality Officer's Full Name], Chief Quality Officer
Seafood Inspection Program
USDC, NOAA, NMFS
1315 East-West Highway
Silver Spring, MD 20910
[Director's Full Name], Director
Division of Seafood Safety (HFS-315)
FDA, Office of Food Safety
5100 Paint Branch Parkway
College Park, MD 20740

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Appendix C: MODEL NOTIFICATION LETTER – Regulatory Action against a Fish or Fishery Product Establishment (actual).

(Appropriate Letterhead)

FOR OFFICIAL USE ONLY

[Date]

[Director's Full Name], Director
 Seafood Inspection Program
 USDC, NOAA, NMFS
 1315 East-West Highway
 Silver Spring, MD 20910

Dear [Title] [Director's Last Name]:

This letter is in reference to the signed Memorandum of Understanding (MOU) between U.S. Department of Commerce, National Oceanic and Atmospheric Administration, and U.S. Department of Health and Human Services, Food and Drug Administration (FDA), dated October 9, 2009, for cooperation and information sharing in the inspection of fish and fishery products and establishments (MOU Number 225-09-0008).

In accordance with section 3.B.3 of the MOU, FDA is informing you that we have taken a [injunction, suspension of registration] action against the firm and/or operator(s) of the firm listed below:

[Firm Name and Address] (FDA FEI # [Firm FEI number])

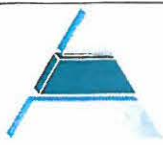
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Access to this non-public information is restricted to authorized FDA and National Marine Fisheries Service (NMFS) employees, agents, and officials who require access to perform their official duties in accordance with the uses of the information as authorized in the MOU, unless authorized in writing by FDA or otherwise required by law.

Please feel free to contact our office with any questions.

Sincerely,
 [Sender's Full Name]
 [Sender's Title]
 [Sender's Office]

cc: [Chief Quality Officer's Full Name], Chief Quality Officer
 Seafood Inspection Program
 USDC, NOAA, NMFS
 1315 East-West Highway
 Silver Spring, MD 20910
 [Director's Full Name], Director
 Division of Seafood Safety (HFS-315)
 FDA, Office of Food Safety
 5100 Paint Branch Parkway
 College Park, MD 20740

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FMD#-029**DATE:
10/31/2011**Appendix D: MODEL NOTIFICATION LETTER – Regulatory Action
against a Fish or Fishery Products (case recommendation)**

(Appropriate Letterhead)

FOR OFFICIAL USE ONLY

[Date]

[Director's Full Name], Director
Seafood Inspection Program
USDC, NOAA, NMFS
1315 East-West Highway
Silver Spring, MD 20910

Dear [Title] [Director's Last Name]:

This letter is in reference to the signed Memorandum of Understanding (MOU) between U.S. Department of Commerce, National Oceanic and Atmospheric Administration, and U.S. Department of Health and Human Services, Food and Drug Administration (FDA), dated October 9, 2009, for cooperation and information sharing in the inspection of fish and fishery products and establishments (MOU Number 225-09-0008).

In accordance with section 3.B.3 of the MOU, FDA is informing you that we intend to take a [seizure] action against the the fish or fishery product(s) listed below:

[Product Information, including Labeling Information and any identifying codes]

Please note that FDA has not made a final decision on this regulatory action. We will inform your office when a final decision is made on this matter.

This non-public information is provided for official use only and may constitute or contain non-public privileged or confidential information which is exempt from public disclosure under 5 U.S.C. Section 552, 18 U.S.C. section 1905, or other applicable statutes.

Access to this non-public information is restricted to authorized FDA and National Marine Fisheries Service (NMFS) employees, agents, and officials who require access to perform their official duties in accordance with the uses of the information as authorized in the MOU, unless authorized in writing by FDA or otherwise required by law.

Please feel free to contact our office with any questions.

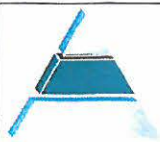
Sincerely,

[Sender's Full Name]

[Sender's Title]

[Sender's Office]

cc: [Chief Quality Officer's Full Name], Chief Quality Officer
Seafood Inspection Program
USDC, NOAA, NMFS
1315 East-West Highway
Silver Spring, MD 20910
[Director's Full Name], Director
Division of Seafood Safety (HFS-315)
FDA, Office of Food Safety
5100 Paint Branch Parkway
College Park, MD 20740

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FMD#-029**DATE:
10/31/2011**Appendix E: MODEL NOTIFICATION LETTER – Regulatory Action
against a Fish or Fishery Products (actual)****(Appropriate Letterhead)**

FOR OFFICIAL USE ONLY

[Date]

[Director's Full Name], Director
Seafood Inspection Program
USDC, NOAA, NMFS
1315 East-West Highway
Silver Spring, MD 20910

Dear [Title] [Director's Last Name]:

This letter is in reference to the signed Memorandum of Understanding (MOU) between U.S. Department of Commerce, National Oceanic and Atmospheric Administration, and U.S. Department of Health and Human Services, Food and Drug Administration (FDA), dated October 9, 2009, for cooperation and information sharing in the inspection of fish and fishery products and establishments (MOU Number 225-09-0008).

In accordance with section 3.B.3 of the MOU, FDA is informing you that we have taken a [seizure, administrative detention, mandatory recall] action against the the fish or fishery product(s) listed below:

[Product Information, including Labeling Information and any identifying codes]

This non-public information is provided for official use only and may constitute or contain non-public privileged or confidential information which is exempt from public disclosure under 5 U.S.C. Section 552, 18 U.S.C. section 1905, or other applicable statutes.

Access to this non-public information is restricted to authorized FDA and National Marine Fisheries Service (NMFS) employees, agents, and officials who require access to perform their official duties in accordance with the uses of the information as authorized in the MOU, unless authorized in writing by FDA or otherwise required by law.

Please feel free to contact our office with any questions.

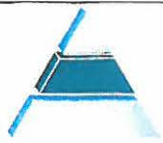
Sincerely,

[Sender's Full Name]

[Sender's Title]

[Sender's Office]

cc: [Chief Quality Officer's Full Name], Chief Quality Officer
Seafood Inspection Program
USDC, NOAA, NMFS
1315 East-West Highway
Silver Spring, MD 20910
[Director's Full Name], Director
Division of Seafood Safety (HFS-315)
FDA, Office of Food Safety
5100 Paint Branch Parkway
College Park, MD 20740



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10/31/2011**

Appendix F: MODEL NOTIFICATION LETTER – Employee or FDA inspector has been asked to Testify in a case in which NMFS is a party.

(Appropriate Letterhead)

FOR OFFICIAL USE ONLY

[Date]

[Director's Full Name], Director
Seafood Inspection Program
USDC, NOAA, NMFS
1315 East-West Highway
Silver Spring, MD 20910

Dear [Title] [Director's Last Name]:

This letter is in reference to the signed Memorandum of Understanding (MOU) between U.S. Department of Commerce, National Oceanic and Atmospheric Administration, and U.S. Department of Health and Human Services, Food and Drug Administration (FDA), dated October 9, 2009, for cooperation and information sharing in the inspection of fish and fishery products and establishments (MOU Number 225-09-0008).

In accordance with section 3.B.9 of the MOU, FDA is informing you that an employee or FDA inspector has been asked to testify in a case in which the National Marine Fisheries Service (NMFS) is a party:

Case:

[Case Information (e.g., case caption, case number, jurisdiction)]

Employee information:

[Employee's Name]

[Employee's Title]

[Employee's Office]

Please feel free to contact our office with any questions.

Sincerely,

[Sender's Full Name]

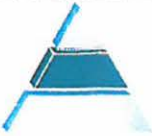
[Sender's Title]

[Sender's Office]

cc: [Chief Quality Officer's Full Name], Chief Quality Officer

Seafood Inspection Program
USDC, NOAA, NMFS
1315 East-West Highway
Silver Spring, MD 20910

[Director's Full Name], Director
Division of Seafood Safety (HFS-315)
FDA, Office of Food Safety
5100 Paint Branch Parkway
College Park, MD 20740

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Appendix G: MODEL INVITATION LETTER – FDA's Office of Regulatory Affairs (ORA) Investigator Certification Program and related activities.

(Appropriate Letterhead)

[Date]

[Training Services contact]
Seafood Inspection Program
USDC, NOAA, NMFS
55 Great Republic Drive
Gloucester, MA 01930

Dear [Title] [Training Services contact's Last Name]:

This letter is in reference to the signed Memorandum of Understanding (MOU) between U.S. Department of Commerce, National Oceanic and Atmospheric Administration, and U.S. Department of Health and Human Services, Food and Drug Administration (FDA), dated October 9, 2009, for cooperation and information sharing in the inspection of fish and fishery products and establishments (MOU Number 225-09-0008).

In accordance with section 3.B.8 of the MOU, FDA is inviting National Marine Fisheries Service (NMFS) personnel to attend the following FDA's Office of Regulatory Affairs (ORA) Investigator Certification Programs or related activity:

[Program/activity Information, including date(s) and location]

FDA currently has [Number of slots] slot(s) available for qualified NMFS personnel.

FDA is unable to reimburse travel and travel related expenses for NMFS personnel.

Please contact our office by [Date] if you have any personnel who would like to participate in this program or activity.

Sincerely,
[Sender's Full Name]
[Sender's Title]
[Sender's Office]

Attachment: Program or Activity (Course) Announcement

cc: [Director's Full Name], Director
Seafood Inspection Program
USDC, NOAA, NMFS
1315 East-West Highway
Silver Spring, MD 20910

[Director's Full Name], Director
Division of Seafood Safety (HFS-315)
FDA, Office of Food Safety
5100 Paint Branch Parkway
College Park, MD 20740

