

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

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| DISTRICT ADDRESS AND PHONE NUMBER<br>158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax:(718) 662-5661 | DATE(S) OF INSPECTION<br>8/15/2016-9/9/2016*<br>FEI NUMBER<br>3008734616 |
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Robert J. Schonfeld, President

|   |   |
|---|---|
| FIRM NAME<br>SM Fish Corp.                                    | STREET ADDRESS<br>5001 Rockaway Beach Blvd  |
| CITY, STATE, ZIP CODE, COUNTRY<br>Far Rockaway, NY 11691-1138 | TYPE ESTABLISHMENT INSPECTED<br>Seafood Processor, Manufacturer, and<br>General Food Manufacturer |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

You did not implement the recordkeeping and verification procedures listed in your HACCP plan.

Specifically during the current inspection on 08/15/2016, 08/17/2016, and 09/08/2016,

A review of your "HACCP PLAN FOR PICKLED HERRING & LOX PRODUCTS," revealed the following deficiencies:

**RECORD KEEPING**

- Your HACCP Plan listed "(b) (4)" and "(b) (4) (b) (4)" as critical control points, with critical limits of a strict formulation for each ingredient used, and a monitoring procedure that requires the (b) (4) (b) (4) of the ingredients (b) (4) used to be recorded. However, no "BATCH PROCESS LOG FOR PICKLED HERRING" was available for different varieties of ready-to-eat herring products packed on production date "8/11/16"

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**VERIFICATION**

- Your HACCP plan identified "(b) (4)" as a critical control point, which lists a "verification" procedure of "(b) (4)" and you have not implemented this verification procedure.
- Your HACCP plan identified "(b) (4)" as a critical control point, which lists a "verification" procedure of "(b) (4)" and you have not implemented this verification procedure.
- Your HACCP plan identified "(b) (4)" as critical control points, and lists "verification" procedures of "calibrate thermometers (b) (4)" for all of the critical control points, and you have not implemented this verification procedure in that your thermometer has not been calibrated since 06/27/2016.
- Your HACCP plan identified "(b) (4)" as a critical control point, which lists a "verification" procedure of "calibrate time/temperature recording

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devices and thermometers (b) (4) " and you have not implemented this verification procedure in that your thermometer has not been calibrated since 06/27/2016.

**OBSERVATION 2**

You do not have a written HACCP plan that outlines controls for a food safety hazard that is reasonably likely to occur.

Specifically,

Upon initiation of the inspection on 08/15/2016, it was determined that your firm processes the following seafood items and your firm did not have a completed and signed HACCP plan in place to control for hazards (including but not limited to physical – metal inclusion, and chemical - allergen) that are reasonably likely to occur.

Frozen/to be cooked:

**(b) (4)**

Ready-to-Eat:

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**(b) (4)**

**OBSERVATION 3**

Your process monitoring equipment is not calibrated to ensure that it reads accurately.

Specifically on 08/17/2016, and 09/08/2016,

- The digital reading on the walk-in refrigerator **(b) (4)** was no less than 6 degrees Fahrenheit higher than what the device was recording on the temperature chart.

**OBSERVATION 4**

You are not monitoring the sanitation conditions and practices with sufficient frequency to assure conformance with Current Good Manufacturing Practices including condition and cleanliness of food contact surfaces, prevention of cross-contamination from insanitary objects and exclusion of pests.

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| <p>Specifically during the current inspection on 08/15/2016, 08/17/2016, and 09/08/2016, it was revealed that:</p> <p>You are not monitoring for the <u>condition and cleanliness of food contact surfaces</u> as evidence by:</p> <ul style="list-style-type: none"> <li>On 08/15/206, 08/17/2016, and 09/08/2016, the inside panel of the (b) (4) door (above ready-to-eat ice) on the ice machine was observed with exposed and cracking foam insulation; pieces of insulation were missing.</li> <li>On 08/15/2016, 08/17/2016, and 09/08/2016, the metal guard on the (b) (4) in the raw fish processing room was observed to be broken with missing metal pieces.</li> <li>On 08/17/2016, after cutting boards used in the raw fish cutting room were cleaned, they were subsequently rested on surfaces that were not cleaned and sanitized.</li> </ul> <p>You are not monitoring for the <u>prevention of cross-contamination from insanitary objects</u> as evidenced by:</p> <ul style="list-style-type: none"> <li>On 08/15/2016 and 08/17/2016, and 09/08/2016, an accumulation of pooled liquid was noted on the floor under and (b) (4) of the ice machine located (b) (4) the doors leading to the (b) (4) (b) (4)</li> <li>On 08/15/2016 the drain line of the wash sink in the herring room was noted to be draining directly onto a metal cover for a grease trap, as well as the (b) (4) room floor.</li> <li>On 08/15/2016 the wash sink in the herring room has a crack in it that is separating the wash sink from the backsplash.</li> </ul> |   |  |  |  |   |
| <b>SEE REVERSE OF THIS PAGE</b>   |   | <table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small><br/>           Raymond M Lam, Investigator<br/>           Christine M Rivera, Investigator<br/>           Erica B Raphael, Investigator         </td> <td style="width: 40%; vertical-align: top;"> <div style="border: 1px solid black; padding: 5px;"> <input type="checkbox"/> Initial signature<br/> <input checked="" type="checkbox"/> Erica B Raphael<br/> <small>Erica B Raphael<br/>Investigator<br/>Signed into Erica B. Raphael - 5</small> </div> </td> </tr> </table> |  | <small>EMPLOYEE(S) SIGNATURE</small><br>Raymond M Lam, Investigator<br>Christine M Rivera, Investigator<br>Erica B Raphael, Investigator | <div style="border: 1px solid black; padding: 5px;"> <input type="checkbox"/> Initial signature<br/> <input checked="" type="checkbox"/> Erica B Raphael<br/> <small>Erica B Raphael<br/>Investigator<br/>Signed into Erica B. Raphael - 5</small> </div> |
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You are not monitoring for the exclusion of pests as evidence by:

- On 08/15/2016 an apparent dead insect was noticed in the walk-in refrigerator.

**OBSERVATION 5**

You did not review some of your critical control point monitoring records within one week after the records were made.

Specifically, during the inspection on 08/15/2016, 08/17/2016, and 09/08/2016,

- A review of your "RECEIVING LOG" for the receipt of raw, refrigerated and frozen fish revealed that these records were not reviewed (b) (4) after the records were made for the following dates:
  - (b) (4)
- A review of your "RECEIVING LOG" for the receipt of raw, refrigerated and frozen fish revealed that these records was not signed and dated as "reviewed" for the following dates:
  - (b) (4)
- A review of your (b) (4) "SANITATION LOG" from (b) (4) had no entries for the week when we checked the paperwork on 08/17/2016. The review of the "DAILY SANITATION LOG" there are no records between (b) (4)
- A review of your (b) (4) "SANITATION LOG" from (b) (4) revealed that this record was not signed and dated as "reviewed."
- A review of your (b) (4) "PACKAGING and LABEL MONITORING LOG" for the following

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products, revealed that these products were not signed and dated as "reviewed":

- On (b) (4) for (b) (4)
- On (b) (4) for (b) (4)
- On (b) (4) for (b) (4)
- On (b) (4) for (b) (4) as well as (b) (4) products.
- On (b) (4) for (b) (4)
- On (b) (4) for (b) (4)
- A review of your "BATCH PROCESS LOG FOR PICKLED HERRING" does not always state the date the process took place. The (b) (4) and (b) (4) were not always listed for the products.
- A review of your "BATCH PROCESS LOG FOR PICKLED HERRING" that expires 08/04 states it was reviewed by (b) (6) on "08/20" a date had not occurred during review of the documents on 08/17/2016.
- A review of your temperature recorder charts for the walk-in refrigerator revealed that record had recorded more than one week based on the number of lines on the chart. The date listed on the recorder chart was only from (b) (4)
- A review of the temperature recorded charts for the walk-in refrigerator revealed only two records (b) (4). There were no records for July

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since our last inspection.

- A review of the temperature recorded charts for the walk-in refrigerator revealed that for the records from (b) (4) they were not signed and dated as reviewed.
- A review of your "Thermometer Calibration Log For Cooler" for this year has not been calibrated or reviewed after (b) (4)

**OBSERVATION 6**

Lack of effective hand cleaning preparations.

Specifically,

- On 08/15/2016, there was no soap in the handwashing sink located in the ready-to-eat kitchen.

**OBSERVATION 7**

Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food and food-contact surfaces.

Specifically,

- On 08/15/2016 and 08/17/2016, employees were observed to clean equipment and utensils including knives, cutting boards and colanders by scrubbing them with soapy mixture and subsequently spraying them with a pressurized hose, but without a subsequent sanitizing step

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prior to using them for food preparation or placing them on a drying rack.

**OBSERVATION 8**

Failure to maintain equipment and utensils in an acceptable condition through appropriate cleaning and sanitizing.

Specifically,

- On 08/15/2016, the cheese slicer in the cheese processing room was observed to have debris located on its surface. Room was cleaned at the end of the previous shift, and has not been used on that day.
- On 08/15/2016, the (b) (4) was observed to have debris still in the (b) (4) mechanism. (b) (4) was stored on a milk crate in the corner of the Prepared Food Kitchen.
- On 08/15/2016, flying insects were noticed landing on the cutting board and knife used in the Prepared Food Kitchen area.
- On 08/15/2016, food debris was observed in the cutting mechanism and around the contents of the (b) (4) is stored on the drying rack next to the Prepared Food Kitchen three compartment sink.

**OBSERVATION 9**

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Effective measures are not being taken to exclude pests from the processing areas and protect against the contamination of food on the premises by pests.

Specifically,

- On 08/15/2016, flying insects were noticed landing on the cutting board and knife used in the kitchen area.

**OBSERVATION 10**

Failure to handle and maintain equipment, containers and utensils used to hold and store food in a manner that protects against contamination.

Specifically,

- 08/15/2016, in the kitchen area, hard boiled eggs were being broken apart in a large mixing bowl resting on a garbage can.

**OBSERVATION 11**

Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition.

Specifically, during the walk-through on 08/15/2016, 08/17/2016, and 09/08/2016

- The bottom corner of the (b) (4) of the entrance, into the (b) (4) room had missing tiles, cracked tiles, and the wood molding was broken. There was also a gap between the wall and the broken wood molding.

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- The floor around the (b) (4) in the corner of the herring preparation area was noted to be uneven allowing debris to collect in this location.
- The floor in the (b) (4) of the herring preparation room, near the floor drain and the metal floor panel was noted with gaps allowing liquid and debris to pool in this area
- The floor in the entry way to the herring preparation area was noted with cracked and uneven concrete. In addition, the cement surfaces where the floor met the walls in this area were cracked and missing pieces.
- The concrete floor surfaces and the walls at the floor-wall junction in the entry to the raw fish processing room were noted to be uneven and cracked allowing liquid to pool.
- The concrete floors throughout the raw fish processing room were pitted allowing liquid to pool on the floor surfaces.

Specifically, during the walk-through on 08/15/2016,

- The Air Conditioning unit in the cheese processing room was observed with liquid leaking onto the food preparation surfaces below.


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**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

|  |   |  |
|--|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER<br>158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax:(718)662-5661 |   | DATE(S) OF INSPECTION<br>8/15/2016-9/9/2016* |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED<br>Robert J. Schonfeld , President  |   | FEI NUMBER<br>3008734616                     |
| FIRM NAME<br>SM Fish Corp.   | STREET ADDRESS<br>5001 Rockaway Beach Blvd  |  |
| CITY, STATE, ZIP CODE, COUNTRY<br>Far Rockaway, NY 11691-1138  | TYPE ESTABLISHMENT INSPECTED<br>Seafood Processor, Manufacturer, and<br>General Food Manufacturer |  |

**\*DATES OF INSPECTION**

8/15/2016(Mon),8/17/2016(Wed),9/08/2016(Thu),9/09/2016(Fri)

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**X** Christine M Rivera

Christine M Rivera  
Investigator  
Signed by: Christine M. Rivera -S


**X** Raymond M Lam

Raymond M Lam  
Investigator  
Signed by: Raymond Lam -S

**SEE REVERSE  
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Raymond M Lam, Investigator  
Christine M Rivera, Investigator  
Erica B Raphael, Investigator

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**X** Erica B Raphael

Erica B Raphael  
Investigator  
Signed by: Erica B. Raphael -S

DATE ISSUED

9/9/2016



The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."