DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

September 13, 2016

Mr. Robert J. Schonfeld, President
SM Fish Corp.
5001 Rockaway Beach Blvd.
Far Rockaway, New York 11691

ORDER: Suspension of Food Facility Registration
Notice of Opportunity for Hearing

Dear Mr. Schonfeld:

The U.S. Food and Drug Administration (FDA) hereby issues this Order to suspend the registration of your food facility, SM Fish Corp., located at 50-01 Rockaway Beach Blvd., Far Rockaway, New York 11691. Your food facility was registered with FDA pursuant to section 415(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 350d(a)) on April 21, 2015. You updated your registration on April 28, 2015. Section 415(b)(1) of the FD&C Act provides, in relevant part, that if FDA determines that a food manufactured, processed, packed, received, or held by a facility registered under section 415 has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility (1) that created, caused, or was otherwise responsible for such reasonable probability; or (2) that knew of, or had reason to know of, such reasonable probability, and packed, received, or held such food.

As discussed further below, FDA has determined that food manufactured, processed, packed, received, or held by your facility has a reasonable probability of causing serious adverse health consequences or death to humans, and that your facility created, caused, or was otherwise responsible for such reasonable probability. FDA is issuing this Order under section 415(b)(1) of the FD&C Act, and the Order is effective immediately upon your receipt. While this Order is in effect, pursuant to section 415(b)(4) of the FD&C Act, no person can import or export food into the United States from your facility, offer to import or export food into the United States from your facility, or otherwise introduce food from your facility into interstate or intrastate commerce in the United States. The introduction or delivery for introduction into interstate commerce in violation of this Order is a prohibited act under section 301(d) of the FD&C Act (21 U.S.C. § 331(d)), which may result in injunction proceedings under section 302 of the FD&C Act (21 U.S.C. § 332) and criminal penalties under section 303 of the FD&C Act (21 U.S.C. § 333). This Order also offers you an opportunity to request an informal hearing, as provided by section 415(b)(2) of the FD&C Act.

The basis for FDA's determination is as follows:

- *Listeria monocytogenes* (*L. monocytogenes*) is a pathogenic organism that has a reasonable probability of causing serious adverse health consequences or death to humans.

- As discussed in detail below, evidence collected by FDA, including environmental samples analyzed by FDA and observations made by FDA during inspections of your facility, establishes the following:

    - Ready-to-eat (RTE) food products including RTE herring in oil; RTE pickled herring products packed in flavored sauce; RTE pickled lox in flavored sauce; and RTE tuna and seafood (imitation crab meat) salads that are manufactured, processed, packed, received or held by SM Fish Corp. are at risk for contamination with *L. monocytogenes* based on the conditions in your facility.

    - The detection of *L. monocytogenes* isolates in your facility shows the widespread and persistent nature of *L. monocytogenes* contamination in your facility. Due to this contamination, FDA has determined that your products have a reasonable probability of causing serious adverse health consequences or death in humans due to *L. monocytogenes* contamination.

    - Your facility created, caused, or was otherwise responsible for this reasonable probability. Specifically, FDA has determined that the conditions within your facility (e.g., the presence of *L. monocytogenes* in various locations throughout the facility and current good manufacturing practice (cGMP) violations that could lead to contamination of your RTE food products) caused this reasonable probability.

<u>Environmental Sampling:</u>

- From August 15, 2016 – September 9, 2016, FDA inspected your facility, located at 50-01 Rockaway Beach Blvd., Far Rockaway, New York 11691. This inspection was initiated to assess actions your firm took after FDA found *L. monocytogenes* within your firm's processing environment during our June 14, 2016-July 6, 2016 inspection. As part of our inspection, FDA collected environmental samples from different areas of your facility, including the kitchen, fish processing room, herring room, cheese slicing room, and the ice maker/machine area. FDA performed analytical testing of those environmental samples. FDA's testing identified twelve (12) swabs that tested positive for *L. monocytogenes* in multiple areas in your facility including one *L. monocytogenes* positive swab on the inner surface of a mixing bowl that contacts food.

- In addition to our most recent findings of *L. monocytogenes*, FDA's inspection ending on May 8, 2015, yielded the identification of fifteen (15) swabs that tested positive

for *L. monocytogenes* in multiple areas in your facility including areas adjacent to food contact surfaces. FDA's subsequent inspection ending July 6, 2016, identified twenty-nine (29) swabs that tested positive for *L. monocytogenes,* and the pathogen was again found in multiple areas in your facility including areas adjacent to food contact surfaces.

- Whole Genome Sequencing (WGS) analysis was conducted on all available environmental *L. monocytogenes* isolates collected at SM Fish Corp. WGS analysis of bacterial human pathogens provides high-resolution data that can directly link clinical isolates to food or environmental sources of bacterial contamination and illness. WGS data can also be used to infer the evolutionary relationships (or phylogeny) within a given set of isolates as it measures each DNA position in a bacterial genome. WGS analysis was conducted on the twelve (12) *L. monocytogenes* isolates obtained from the FDA environmental samples collected during the August 15, 2016 – September 9, 2016 inspection; the twenty-nine (29) *L. monocytogenes* isolates obtained from the FDA environmental samples collected during the June 14, 2016-July 6, 2016 inspection; and the fifteen (15) *L. monocytogenes* isolates obtained from the FDA environmental samples collected during the April 20, 2015-May 8, 2015 inspection. The WGS phylogenetic analysis finds that there are at least seven (7) different strains of *L. monocytogenes* present in your facility. Additionally, FDA collected environmental isolates from all FDA inspections referenced in this document (ending on September 9, 2016, July 6, 2016, and May 8, 2015) that are genetically identical to one (1) strain that is a genetic match for the pathogen found in four (4) listeriosis clinical illnesses.

- The detection of *L. monocytogenes* from environmental isolates that genetically match the four (4) incidents of human illness referenced above indicates that the strain of *L. monocytogenes* found in your facility is capable of causing life-threatening, invasive listeriosis.

- Over a two year period, three (3) FDA inspections isolated the same three (3) strains of *L. monocytogenes* in your processing environment, which indicates your firm's cleaning practices have been unable to eradicate a pathogen capable of causing severe health consequences.

- The multiple findings of *L. monocytogenes* throughout your processing facility are significant because it indicates widespread and persistent harborage of *L. monocytogenes* contamination. The most recent finding of *L. monocytogenes* on a direct food contact surface is of particular concern. Further, the presence of *L. monocytogenes* at a significant rate in a wet processing environment with a high amount of manual packing is likely to lead to cross contamination and transmission of the pathogen to the finished RTE product. FDA's environmental findings further support that your firm's sanitation practices are ineffective and that your firm lacks an understanding of how to control or eliminate *L. monocytogenes.*

Current Good Manufacturing Practice (cGMP) Violations:

- During FDA's inspection, the investigators observed serious violations of the cGMP requirements for food that cause your RTE seafood products to be adulterated within the meaning of section 402(a)(4) of the FD&C Act, in that the foods have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. These conditions and practices, in conjunction with the above-described findings related to *L. monocytogenes,* create a reasonable probability that food manufactured, processed, packed, or held in your facility is contaminated with *L. monocytogenes.* Your RTE seafood products are not subjected to a kill step prior to distribution; therefore there is a reasonable probability of such food causing serious adverse health consequences or death to humans. Your firm lacks the adequate implementation of sanitation practices to effectively control or eliminate *L. monocytogenes* in your processing environment. Due to the widespread and persistent contamination of your facility with *L. monocytogenes* and our recent *L. monocytogenes* findings, your practices are not effective to control contamination in your processing environment.

- Your firm's ineffective cleaning and sanitizing procedures in conjunction with the use of pressurized spray hoses and squeegees to move standing water into drains is of serious concern. During both inspections conducted in 2016, your firm used pressurized hoses within your processing facility. Specifically:

    - During the inspection ending on September 9, 2016, employees were observed cleaning equipment and utensils including knives, cutting boards, and colanders by scrubbing them with soapy mixture and subsequently spraying them with a pressurized hose, but employees did not subsequently sanitize prior to using the equipment for food preparation or placing them on a drying rack.

    - During the inspection ending on July 6, 2016, your firm used hoses with spray nozzles throughout the facility to spray down and rinse equipment and the floors.

  In a wet processing environment, using spray nozzles and squeegees can facilitate the movement of *L. monocytogenes* contamination within a facility. Aerosols from a high pressure hose used on floors or unclean equipment have been shown to linger in the air for periods of hours and can allow for the re-contamination of previously cleaned and sanitized food contact surfaces. Due to the prevalence and persistence of *L. monocytogenes* in your facility, your cleaning and sanitizing procedures may cause the spread and re-contamination of *L. monocytogenes* within your facility.

- Additionally, our investigators observed the following significant deficiencies:

    - During both inspections conducted in 2016, your firm has consistently failed to exclude pest from your processing environment. Specifically:

- During the inspection ending on September 9, 2016, flying insects were noticed landing on the cutting board and knife used in the Prepared Food Kitchen area.

- During the inspection ending on July 6, 2016, an accumulation of pooled liquid, some of which contained too numerous to count dead flies, was noted on the floor under and in front of the ice machine located outside the doors leading to the kitchen and fish cutting room. Employees were noted to be walking through the liquid and dragging plastic carts filled with fish through this liquid.

- During both inspections conducted in 2016, your firm has consistently failed to fix broken metal guards with missing pieces of metal on your fish grinder in the raw fish cutting room. The missing piece of metal guard and cracks within the metal create a challenge to adequately clean and sanitize and could present a possibility for potential harborage areas for *L. monocytogenes.*

- During the most recent inspection, condensate was observed from the air conditioning unit leaking onto the food preparation surfaces below in the cheese processing room. Condensate may foster the growth, contribute to the spread, and/or allow for the development of harborage sites for pathogens, such as *L. monocytogenes.*

Based on the current conditions of the facility, FDA concludes that unless and until SM Fish Corp. has completed and implemented certain corrective actions, food manufactured, processed, packed, received, or held at the SM Fish Corp. facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

Opportunity for an Informal Hearing

Pursuant to section 415(b)(2) of the FD&C Act, you may request an informal hearing on the actions required for reinstatement of your facility's registration and why your facility's registration should be reinstated.

Section 415(b)(2) of the FD&C Act provides in relevant part that a registrant subject to an order of suspension under section 415(b) must be provided with an opportunity for an informal hearing, to be held as soon as possible, but not later than two (2) business days after the issuance of the order. To request an informal hearing to be held within two (2) business days after the issuance of this Order, you must submit your request, in writing, to the FDA contact person identified in this Order [by approximately 24 hours from the anticipated time of issuance of this Order] on the first business day following receipt of this Order.

Alternatively, section 415(b)(2) of the FD&C Act provides that an informal hearing may be held at some other time period, as agreed upon by FDA and the registrant. In order to request a hearing to be held at a later time, as agreed upon by the registrant and FDA, you must

submit your request, in writing, to the FDA contact person identified in this Order no later than 5:00 pm EDT on the third business day following receipt of this Order. If you do not submit a written hearing request within that time, your facility will be deemed to have waived its right to the opportunity for an informal hearing.

If you request an informal hearing, a Presiding Officer (PO) as defined in 21 CFR 16.42 will be designated, and you will be notified of that individual's identity and contact information. If the PO determines that a hearing is not justified, the PO will provide you and FDA written notice of this determination that explains the reasons for denying your request for a hearing. If the PO grants your request for an informal hearing, at the informal hearing you will have the opportunity to address the actions required for reinstatement of your facility's registration and to explain why the registration should be reinstated. The informal hearing will be conducted in accordance with the procedures in 21 CFR part 16, Regulatory Hearing Before the Food and Drug Administration, to the extent that such procedures are not in conflict with the procedures specified in section 415(b) of the FD&C Act. The informal hearing will be a closed hearing to protect information not available for public disclosure, as provided by 21 CFR 16.60.

Under section 415(b)(4) of the FD&C Act, if the registration of a facility is suspended under section 415(b), no person can import or export food into the United States from such facility, offer to import or export food into the United States from such facility, or otherwise introduce food from such facility into interstate or intrastate commerce in the United States. Accordingly, until this Order is vacated and your facility's registration is reinstated, you or any other individual may not introduce food from your facility, which includes all of the buildings at your facility, into interstate or intrastate commerce in the United States. This prohibition includes food that is currently still under your control that was produced before or after you received this Order. This Order does not prevent or affect any on-going food safety related recalls and shipments of such food back to your facility. However, once you have received the returned food, you may not introduce such food from your facility into interstate or intrastate commerce.

If you do not want to request an informal hearing, but you want to have your registration reinstated in part by submitting a corrective action plan to FDA that demonstrates how you plan to correct the conditions found by FDA, please contact the FDA contact person identified in this Order.

You may submit your written request for an informal hearing or your written response to this Order by any mode of written communication (e.g., mail, email, delivery service, personal delivery) to the following FDA contact person:

LCDR Matthew Palo, New York Acting District Director
158-15 Liberty Ave
Jamaica, NY 11433
Matthew.Palo@FDA.HHS.GOV
(718) 662-5552

In your submission, you should include your mailing address, phone number, email, and any other relevant contact information. You should promptly contact the FDA contact person by phone or email if you have any questions regarding this Order.

Sincerely,

Robert M. Califf, M.D.
Commissioner of Food and Drugs