



March 11, 2014

Ms. Ana Roos, President
Roos Foods Inc.
251 Roos Lane
Kenton, DE 19955

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

Dear Ms. Roos:

The U.S. Food and Drug Administration (FDA) hereby issues this Order to suspend the registration of your food facility, Roos Foods, Inc. (Roos), located at 251 Roos Lane, Kenton, DE 19955. 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 June 4, 2013. 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 may 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) or 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:

- In February 2014, the Centers for Disease Control and Prevention (CDC) and FDA collaborated to investigate a multistate outbreak of *Listeria monocytogenes*

(*L. monocytogenes*). CDC has reported a total of eight (8) persons infected with the outbreak strain of *L. monocytogenes*; one of those individuals is now deceased. Soft cheeses manufactured by Roos have been identified by FDA and CDC as a likely source of this outbreak.

- *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 in response to this outbreak, including environmental samples analyzed by FDA, finished product samples analyzed by Maryland and Virginia state laboratories, and observations made by FDA during an inspection of your facility, establishes the following:
 - Cheese products manufactured, processed, packed, or held by your facility are contaminated with *L. monocytogenes*, or are at risk for contamination with *L. monocytogenes* based on the conditions in your facility.
 - The finding of *L. monocytogenes* isolates in your facility shows the widespread and persistent nature of *L. monocytogenes* contamination in Roos processing 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.
 - 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 raw materials and finished product) caused this reasonable probability.

Environmental and Soft Cheese Product Samples:

- From February 18, 2014 to March 4, 2014, FDA inspected your facility located at 251 Roos Lane, Kenton, DE 19955. As part of our inspection, FDA collected environmental samples from different areas of your facility, including the cheese processing room and various pieces of equipment. FDA performed analytical testing of those environmental samples. FDA's testing identified 12 swabs that tested positive for *L. monocytogenes*, including two *L. monocytogenes* positive swabs found on food contact surfaces of the cutting board and inside the cheese press. Additional positive swabs were found around the main processing room where soft cheese products are stored and manufactured.
- Analysis using pulsed-field gel electrophoresis (PFGE) showed that 11 of the 12 *L. monocytogenes* isolates obtained from the FDA environmental samples collected on February 18, 2014, were indistinguishable from the clinical isolates associated with the *L. monocytogenes* outbreak. The PFGE pattern for the clinical isolates and the environmental samples are indistinguishable by a two-enzyme pattern combination, which is strengthened by the *L. monocytogenes* whole genome sequence that shows the clinical isolates originated from a single bacteria lineage and that it is reasonably likely that the lineage shares the same geographic locale.

- As part of the outbreak investigation, Maryland and Virginia state agencies collected unopened, finished product samples of cheese products manufactured and distributed by Roos from different retail establishments. Maryland performed analytical testing of these finished product samples that identified Cuajada en Terron cheese; Santa Rosa de Lima brand Cuajada en Terron, Cuajadita Casera, and Queso Fresco cheeses; Amigo brand Queso Fresco and Cuajadita Casera cheeses; and Mexicana brand Cuajadita Fresca cheese products that tested positive for *L. monocytogenes*. Virginia analyzed finished product packages of Santa Rosa de Lima brand Cuajada en Terron (Fresh Cheese Curd) that also tested positive for *L. monocytogenes*.
- Analysis using PFGE showed that *L. monocytogenes* isolates obtained from the finished cheese product samples collected by Maryland and Virginia were indistinguishable from the clinical isolates associated with the *L. monocytogenes* outbreak discussed above. The PFGE pattern for the clinical isolates and the intact cheese samples are indistinguishable by a two-enzyme pattern combination, which is strengthened by the *L. monocytogenes* whole genome sequence that shows the clinical and the intact cheese sample isolates originated from a single bacteria lineage and that it is reasonably likely that the lineage shares the same geographic locale. These results also indicate that the pervasive and widespread nature of *L. monocytogenes* contamination in your facility caused *L. monocytogenes* contamination in finished products, which creates a reasonable probability of these products causing serious adverse health consequences or death in humans.

Current Good Manufacturing Practice (CGMP) Violations:

- During FDA's inspection of your facility, our investigators observed serious violations of the CGMP requirements for food in your facility's food production area. These violations cause your cheese 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. Further, 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*. Therefore, there is a reasonable probability of such food causing serious adverse health consequences or death to humans.
- Specifically, our investigators observed the following:
 - Water was raining from the facility's roof into the facility, including onto the cheese processing equipment and storage tanks. Specifically,
 - Water was dripping from the ceiling onto 50 pound paper bags of salt, cheese product packaging materials, and labels stored in an ambient storage room adjacent to the sour cream packaging area.
 - Standing water was on the floor throughout the cheese curd processing room in proximity to the cheese vats, the high-temperature short-time (HTST) pasteurizer, and milk storage tanks.

Employees in the cheese curd processing room must walk through the finished product packaging area and the sour cream packaging area to access the break room and restrooms.

- Standing water was in storage rooms adjacent to the processing areas including a room where you store packaging, ingredients, and labels.
- The metal roof/ceiling and metal supports in the cheese curd manufacturing room and cheese packaging room exhibit extensive oxidation, including a rusted appearance with metal flaking visible. This condition precludes effective cleaning and sanitizing.
- On February 19, 2014, we observed rust colored, metal-like particles on a stainless steel table in the cheese packaging room.
- On February 18, 2014 and again on February 19, 2014, rust-colored water droplets were falling from the metal ceiling, the metal support beams, pipes, and other infrastructure above the cheese vats and onto food processing equipment in the cheese curd manufacturing room and were also falling from the ceiling in the cheese packaging room, the sour cream manufacturing area, and from the ceilings in the storage rooms adjacent to the processing areas. The water was pooling on food contact and non-food contact surfaces, including four open-top cheese curd manufacturing vats, food handling containers, tools used to manufacture cheese, and product packaging materials and equipment.
- Tools, portable plastic tubs, knives, and other food handling equipment were stored in the basin of the cheese press. Water dripping from the rusted, metal ceiling and supporting beams had pooled into equipment crevices and surfaces. The rust-colored water stained the equipment and plastic food storage containers with rust-like color.
- Food residues were found on equipment after cleaning and sanitation operations had been performed, including residues from previous production runs on door handles, equipment control switches, and hand grip areas on tools and equipment stored in the cheese curd manufacturing room.
- Openings to milk storage tanks and transfer piping were not capped to prevent contaminants from entering or contaminating food contact surfaces. There were residues from previous use on the inner and exterior surfaces of the vats and the protective shields covering the agitator equipment above the open vats used to manufacture cheese curd.
- The facility's processing and storage equipment has uncleanable surfaces, including surfaces with rust and rough concrete. These surfaces present harborage areas for *L. monocytogenes*, including:
 - The cheese curd vat located between the cheese press and the longer vat along the north wall of the room had gaps and holes in the exterior panels generated by oxidation of the metal and chemical deterioration of the panels.

- The concrete floor surface area near the cheese vat drain ports and in areas adjacent to floor drains has deteriorated.
- The door handles and surrounding areas of the door handles used to access the in-process product storage rooms exhibited oxidized metal and had areas with peeling paint.
- At least three wash-down hoses with hand grip spray nozzles used in your manufacturing and packaging rooms were not equipped with proper backflow prevention devices. The wash-down hose on the north side of the cheese curd manufacturing room was stored on the floor.

Based on the current conditions of the facility and past management policies and actions, FDA concludes that unless and until Roos has completed and implemented certain corrective actions, food manufactured, processed, packed, or held at your facility has a reasonable probability of causing serious adverse health consequences or death to humans.

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 12:00 pm EDT 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.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that warrants a hearing. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Commissioner or her delegate determines that no genuine and substantial issue of fact had been raised by the material submitted. A hearing will not be granted on issues of policy or law. Accordingly, your request for a hearing should include information that you believe shows that there is a genuine and substantial issue of fact that warrants a 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. The PO may deny your request for a hearing if the PO determines that you have not raised a genuine or substantial issue of fact by the material submitted in your hearing request, or if you failed to request the hearing within the time frame stated in this Order. 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.

If you wish to request an informal hearing, but do not wish to request that the hearing be held orally, you should contact the FDA contact person identified in this Order and send a written response containing the basis for your request for an informal hearing to the FDA contact person by 5:00 pm EDT on the third business day following receipt of this Order. Your submission should state that you waive your opportunity for an oral informal hearing and that you want your request to be based solely on your written response and other information available to FDA for an informal hearing.

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 still under your control that was produced before and after you received this Order. This Order does not affect your ongoing recall of Grade A sour cream and cheese products and shipments of such products back to your facility. However, once you have received the returned food products, you may not introduce such products from your facility into interstate or intrastate commerce.

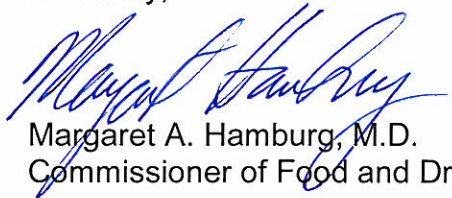
If you do not want to request an informal hearing, but you want to have your registration reinstated, you must submit a corrective action plan to FDA that demonstrates how you plan to correct the conditions found by FDA. Submit your corrective action plan to the FDA contact person identified in this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

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:

Karyn M. Campbell, Acting District Director
Philadelphia District
US Customs House, Room 900
200 Chestnut Street
Philadelphia, PA 19106
Karyn.Campbell@fda.hhs.gov
(215) 717-3731

In your submission, you should include your mail 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,

A handwritten signature in blue ink, appearing to read "Margaret A. Hamburg".

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs