U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

5001 Campus Drive
College Park, MD 20740

March 27, 2017

Mr. Robert C. Carl, President
Dixie Dew Products, Inc.
1360 Jamike Avenue
Erlanger, KY 41018

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

Dear Mr. Carl:

The U.S. Food and Drug Administration (FDA) hereby issues this Order to suspend the registration of your food facility, Dixie Dew Products, Inc. (Dixie Dew), located at 1360 Jamike Avenue, Erlanger, Kentucky 41018. 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 May 22, 2013. You updated your registration on December 7, 2016. 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/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.

As discussed in greater detail below, FDA's determination 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 is based on three factors. First, food products manufactured at your Erlanger, Kentucky facility have been identified as the likely source of a multistate outbreak of pathogenic *E. coli*, leading to 10 hospitalizations and 7 cases of hemolytic uremic syndrome (HUS). Second, during a recent inspection of your facility, FDA documented that your firm was manufacturing, preparing, and holding ready-to-eat food products under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. Third, although you have responded to the agency's inspectional observations by taking a number of corrective actions, we do not believe your response to date is adequate to address the risks caused by your facility. Because your firm's soy nut butter products are ready-to-eat (i.e., consumers do not subject them to a further processing kill step) and have a low water activity and high fat content, if such products are contaminated with

E.coli, including *E.coli* O157:H7, then the *E. coli* would be able to survive for the duration of the products' shelf life.

E. coli O157:H7

- *E. coli* O157:H7 is a pathogenic organism that can contaminate food. The spectrum of illnesses caused by *E. coli* O157:H7 can range from asymptomatic infection and non-bloody diarrhea to severe manifestations, such as bloody diarrhea (hemorrhagic colitis), thrombotic thrombocytopenic purpura (TTP), and HUS. Patients with *E. coli* O157:H7 infections that develop HUS may experience hemolytic anemia (abnormally low hematocrit or red blood cell count due to destruction of red blood cells), thrombocytopenia (abnormally low platelet count), and renal failure. Although most patients recover from HUS within 7-10 days, a proportion (as many as 40%) experiences some long-term abnormality of renal function, not requiring dialysis or kidney transplantation. However, some patients with HUS require permanent dialysis and kidney transplantation. Additionally, some patients with HUS experience strokes and about 3-5% die.

- Children and elderly persons are at the highest risk for severe illness resulting from infection with *E. coli* O157:H7.

- Only a small number (<50) of *E. coli* O157:H7 may be required to cause disease.

- When consumed, *E. coli* O157:H7 has a reasonable probability of causing serious adverse health consequences or death to humans.

Epidemiological Findings

- In March 2017, the Centers for Disease Control and Prevention (CDC) and FDA collaborated to investigate a multistate outbreak of *E. coli* O157:H7. As of March 24, 2017, CDC has reported twenty three (23) persons across nine (9) different states infected with the outbreak strain of *E. coli* O157:H7. Ten (10) case patients have been hospitalized, and seven (7) have developed HUS. Twenty (20) of the case patients reported eating or being served (b) (4) SoyNut Butter or (b) (4) SoyNut (b) (4) coated with (b) (4) SoyNut Butter before the onset of their illnesses. The remaining three (3) case patients denied eating (b) (b) (4) SoyNut Butter; however, all three (3) of those case patients attended the same daycare facility in Oregon as one confirmed case patient who ate the implicated product at home.

- Samples of (b) (4) SoyNut Butter have been tested by several state departments of health (i.e., the California Department of Public Health (CDPH), the Oregon Public Health Division (OPHD), and the Washington Department of Health (WDH)) and been found positive for *E. coli* O157:H7. Specifically, CDPH collected unopened, finished product samples of (b) (4) SoyNut butter products manufactured and distributed from different retail establishments that tested positive for *E. coli* O157:H7. OPHD and WDH also collected consumer samples from case patients' homes that tested positive for *E. coli* O157:H7.

- CDPH, OPHD, and WDH analysis on 6 consumer and 2 retail samples identified an indistinguishable Pulse Field Gel Electrophoresis (PFGE) pattern of *E. coli* O157:H7 to the human clinical cases. PFGE is a molecular fingerprint technique used to classify bacteria based on restriction sites within the bacterial genome beyond the species level.

- The positive test results indicate *E. coli* O157:H7 contamination in (b) (4) SoyNut Butter finished products, which could cause serious adverse health consequences or death in humans.

- Based on the foregoing, CDC and FDA identified (b) (4) SoyNut Butter products as the likely source of this outbreak. Dixie Dew is the sole manufacturer of (b) (4) SoyNut Butter products, and they are made at Dixie Dew's Erlanger, Kentucky facility.

Insanitary Conditions at Dixie Dew's Facility

- FDA inspected your facility between March 3 and 15, 2017. During FDA's inspection, the investigators observed grossly insanitary conditions that cause your firm's soy nut butter 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 contaminated with filth and/or rendered injurious to health. As described in the Form FDA 483 provided to Dixie Dew at the close of the inspection, the insanitary conditions observed by the FDA investigators include, but are not limited to, the following:

  - Throughout the whole production run of (b) (4) SoyNut Butter (b) (4) on 3/6/17, a clear liquid substance was observed dripping intermittently from a hole in a ceiling tile in the Soy Butter processing room, landing on the processing room floor, and splashing on food manufacturing equipment below. This observation is of significant concern because a ceiling hole could be an indication of a leaky roof and a pathway for possible contaminants, including pathogenic *E. coli,* to enter the facility.

  - Your facility had mechanical forklifts operating both outside the building for waste disposal and throughout the facility, including the soy nut butter production and packaging rooms. Your Plant Manager stated that these forklifts are never cleaned. Areas that contain waste disposals are susceptible to pest and rodent harborage. Pest and rodents are known to carry pathogenic *E. coli*, and the forklifts that were being used by your facility to transport waste to and from the production environment for a RTE food makes this practice a potential source for bringing pathogenic *E. coli* into the facility. Additionally, there was no control regarding employee foot traffic in and out of your processing facility. Just as the forklifts were noted to be moving in and out of the facility to and from the waste disposal area outside of the facility, personnel foot traffic was observed doing the same thing and could also be a potential source for bringing pathogenic *E. coli* into the facility, as well as for moving around any *E. coli* that is in your facility.

  - After handling manufacturing equipment that was in contact with the processing room floor, an employee washed his hands in a hand wash station that did not have hand soap or hot water prior to continuing with the manufacturing process, which involved handling packaged food ingredients and finished product containers and packaging. There was no hot water in the hand washing sink or the sink located in the soy nut butter processing room, and, according to your maintenance supervisor, the hot water tank for those sinks had been out of repair for two years. A food manufacturing facility that does not provide adequate hand washing stations to its employees, and an employee who has bad hygienic practices, both could lead to contamination of food with pathogenic *E. coli*.

  - Food contact surfaces, floors, walls, and ceilings in the soy nut butter processing and packaging rooms were heavily coated with soy nut butter build-up from previous production runs. Specifically, old soy nut butter was observed on the blender, (b) (4), kettle, and (b) (4). Your firm does not routinely wash and sanitize smaller pipes, pipe fittings, gaskets, seals, or the rubber (b) (4) plug when broken down following a production run. Additionally, your firm informed the investigators that the last full clean of the soy nut butter production room was in approximately December 2015. The only other type of periodic cleaning performed by your facility involves use of hot oil, not detergents and sanitizers. Your facility's cleaning SOP mentioned having cleaning logs for all processing

equipment, floors and walls, the lab, office, break room, and restrooms; however, no cleaning logs were being kept at the time of the inspection and in fact had not been maintained in several years. Poor sanitation practices and poor equipment maintenance can lead to environmental contamination and finished product contamination with pathogens, including *E. coli*.

- The (b) (4) machine, used for fine mixing and the (b) (4) frequently (e.g., once or twice a day) shuts off during production due to amperage overload. This intermittent interruption in processing can affect the development of the desired (b) (4) for the in-process product. Additionally, the (b) (4) thermometer used to measure the (b) (4) has never been verified for accuracy, and the temperature probe and chart recorder engineered to verify and record (b) (4) are not functioning properly and have not been used for over one year. Your facility's failure to appropriately calibrate its thermometer and have properly functioning equipment is a significant concern regarding your ability to administer an effective (b) (4).

- Further evidence of insanitary conditions at your facility was recently provided by the State of Maryland Department of Health and Mental Hygiene Lab, which reported the results of its testing of unopened jars of (b) (4) SoyNut Butter. The results show product for the three different Best by Dates (i.e., 122718, 010919, and 011119), with >1,100 MPN coliforms per gram and > 1,100, 240, and 3.6 MPN fecal coliforms, respectively. Coliform bacteria are heat sensitive and would be eliminated by the Dixie Dew described (b) (4) process if properly applied. Fecal coliform bacteria are indicative of fecal contamination. Therefore, these data – which pertain to products your facility manufactured in December 2016 and January 2017 - clearly support the conclusion that your firm was producing food under insanitary conditions and show the potential impact of the observed lack of cleaning and sanitation at the Dixie Dew facility.

- We acknowledge that, on March 20, 2017, your facility submitted its response to the Form 483, outlining corrective actions that Dixie Dew has taken and/or is planning to take. These corrective actions include repair of the leak in the ceiling tile, labeling forklifts on where they may be used and promising to clean them, installing a new hot water heater and soap dispenser for the hand washing sinks, retraining employees on hand washing, and repairing the floor, cooler, and ceiling tiles. Nevertheless, review of Dixie Dew's response found that your firm has not taken sufficient corrective actions to give adequate assurance that products manufactured and distributed by your facility are not at risk for contamination with *E.coli* O157:H7. For example,

  - Your firm did not commit to calibrate the thermometer that is used to measure and verify the adequacy of your kill step.

  - Although you indicated that Dixie Dew disassembled and cleaned its equipment, you did not state that the equipment had been sanitized. Indeed, the standard operating procedure you submitted lacked details on the detergents and sanitizing chemicals to be used, what is to be cleaned and sanitized, and what equipment will be disassembled prior to cleaning and sanitizing. You also did not describe any means of verifying the effectiveness of the cleaning and sanitization procedures other than visual inspection, which is not adequate for pathogen control.

  - Your response did not discuss any plan for controlling foot traffic in your production facility.

- Given the epidemiological findings showing that your food products are the likely source of an outbreak of *E. coli* O157:H7 and the current conditions of the facility, FDA concludes that unless and until Dixie Dew has completed and implemented certain corrective actions, food manufactured, processed, packed, received,

or held at the Dixie Dew 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 within 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 EST 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 designated Presiding Officer (PO), as defined in 21 CFR 16.42, 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, 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 during the informal hearing. The informal hearing will be conducted in accordance with the procedures set forth in 21 C.F.R. 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 pursuant to 21 C.F.R. 16.60.

Under section 415(b)(4) of the FD&C Act, if a food facility's registration 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:

Steven Barber, Cincinnati Acting District Director
FDA Cincinnati District Office and Forensic Chemistry Center
6751 Steger Drive
Cincinnati, OH 45237
Steven.Barber@FDA.HHS.GOV
(513) 679-2700 EXT 2116

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

Sincerely,

Dr. Stephen M. Ostroff
Acting Commissioner of Food and Drugs