UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

UNITED STATES OF AMERICA, Plaintiff, v. FRESHY FOODS, LLC, a limited liability company, TEAM FRESH & GO, LLC, a limited liability company, FLOYD D. JAMES and IDA M. JAMES, individuals, Defendants.	)	CIVIL NO. 24-cv-01487 SECTION H "3" JUDGE JANE TRICHE MILAZZO MAGISTRATE EVA J. DOSSIER

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America on behalf of the Food and Drug Administration ("FDA"), (collectively "U.S.") by its undersigned counsel, having filed a Complaint for Permanent Injunction against Freshy Foods, LLC ("Freshy Foods"), a Louisiana limited liability company, Team Fresh & Go, LLC, a limited liability company, and Floyd D. James and Ida M. James, individuals (collectively ("Defendants"), and Defendants having appeared and answered the complaint, and both parties having consented to entry of this Decree without contest, it is hereby stated that and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. The Complaint alleges that Defendants violate, 21 U.S.C. § 331(a), by introducing

or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of food within the meaning of 21 U.S.C. § 321(f), namely ready-to-eat ("RTE") products, including, but not limited to, sandwiches, wraps, salads, fruit cups, and snack cups, that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed (including repacked), or held under insanitary conditions whereby they may have been rendered injurious to health.

4. The Complaint alleges Defendants violate 21 U.S.C. § 331(k), by causing such articles of food, within the meaning of 21 U.S.C. § 321(f), namely RTE products, including, but not limited to, sandwiches, wraps, salads, fruit cups, and snack cups, that are held for sale after shipment of one or more of their components into interstate commerce, to become adulterated under 21 U.S.C. § 342(a)(4), in that they have been prepared, packed (including repacked), or held under insanitary conditions whereby they may have been rendered injurious to health.

5. The provisions in this Decree apply only to food regulated by the United States Food and Drug Administration ("FDA") and do not apply to food regulated by the United States Department of Food and Agriculture ("USDA").

6. The term "food" is defined in 21 U.S.C. § 321(f). For purposes of this Decree, the term "FDA-regulated food" includes all food regulated by FDA, including but not limited to, food ingredients, in-process, and finished food and excluding: any "meat food product," as defined by the Federal Meat Inspection Act, 21 U.S.C. § 601(j); any "poultry product," as defined by the Poultry Products Inspection Act, 21 U.S.C. § 453(f); any "egg product," as defined by the Egg Products Inspection Act, 21 U.S.C. § 1033(f).

7. For the purposes of this Decree, "FDA-regulated food operations" includes preparing, processing, packing (including repacking), and/or distributing any FDA-regulated food.

8. For the purposes of this Decree, "pre-packaged FDA-regulated food" refers to food that is in fully sealed packages that was manufactured by someone other than Defendants at a facility other than Defendants' Facility (defined at paragraph 9 below) and for which the internal sealed package remains uncompromised, such that the food contained in the internal sealed package is not exposed to the Defendants' Facility's environment.

9. "Facility" refers to Defendants' facility located at 508 Time Saver Avenue, Elmwood, Louisiana 70123, and/or any other location(s) at or from which Defendants, now or in the future, directly or indirectly receive, prepare, process, pack (including repack), hold, and/or distribute articles of food.

10. The "CGMP and PC Rule" shall refer to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule set forth at 21 C.F.R. Part 117.

11. "Corporate Defendants" shall refer to Freshy Foods, LLC and Team Fresh & Go, LLC and any of their successors, assigns, subsidiaries, franchises, affiliates and/or "doing business as" entities.

12. As of the entry of this Decree, Defendants represent that they have withdrawn their registration with FDA under 21 U.S.C. § 350d and that they intend to manufacture USDA-regulated food unless they comply with all of the terms herein. Defendants also represent that as of entry of this Decree, they are not directly or indirectly preparing, processing, packing (including repacking), and/or distributing any FDA-regulated food at or from any location. Nothing in paragraph 14 of this Decree shall preclude Defendants from receiving, holding, repacking, and distributing pre-packaged FDA-regulated food that is in compliance with the Act and FDA regulations and that Defendants purchase from a third party or parties, so long as Defendants do

not compromise the internal sealed food articles and re-register with FDA in accordance with 21 U.S.C. § 350d.

13. With the exception of the limited activities noted in paragraph 12, if Defendants intend to resume any FDA-regulated food operations, they must first: register with FDA in accordance with 21 U.S.C. § 350d; notify FDA in writing at least sixty (60) business days in advance of resuming operations; and comply with paragraphs 14(A) – (F) and (H) of this Decree. The notice shall identify the type(s) of FDA-regulated food that Defendants intend to prepare, process, pack (including repack), and/or distribute at or from any Facility. Defendants shall not resume FDA-regulated food operations until FDA has inspected Defendants' Facility and operations pursuant to paragraph 14(G), Defendants have paid the costs of such inspections as required by paragraph 14(H), and Defendants has received written notice from FDA as required by paragraph 14(I), and Defendants shall resume FDA-regulated food operations only to the extent authorized in FDA's written notice.

14. With the exception of the limited activities noted in paragraph 12, upon entry of this Decree, Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, affiliates, franchisees, and "doing business as" entities) (hereinafter, collectively referred to as "Associated Persons"), who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly preparing, processing, packing (including repacking), and/or distributing FDA-regulated food at or from their Facility unless and until:

A. Defendants retain, at Defendants' expense, an independent expert(s) (the

"Expert(s)"), who is without any personal or financial ties (other than a retention agreement) to Defendants or their families and who, by reason of background, education, training, and/or experience is qualified to:

(1) Develop and ensure the adequate implementation of a written Pathogen Control Program;

(2) Establish methods, facilities, and controls at Defendants' Facility to ensure that food is received, prepared, processed, packed, held, and/or distributed in compliance with the CGMP & PC Rule; and

(3) Inspect the Facility to determine whether Defendants' methods, processes, and controls are continuously operated and administered in conformity with this Decree, the Act, and the CGMP and PC Rule.

Defendants shall notify FDA in writing of the identity and qualifications of the Expert(s) within three (3) business days after retaining such expert(s);

B. Defendants retain, at their expense, an independent laboratory (the "Laboratory") having no personal or financial ties (other than the retention agreement) to Defendants or their families, which is qualified to analyze environmental and food samples collected at Defendants' Facility for the presence of *Listeria monocytogenes* ("*L. mono*") in a manner that is acceptable to FDA. Within two (2) business days after retaining the Laboratory, Defendants shall provide FDA with a copy of the service contract, which shall contain provisions acceptable to FDA for conducting environmental and FDA-regulated food analyses;

C. Defendants' Expert(s), in consultation with the Laboratory and after reviewing all of the FDA inspectional observations from April 2014 to the present, shall develop a written Pathogen Control Program to FDA's satisfaction. The Pathogen Control Program shall

include, at a minimum:

(1) A written sanitation control program that establishes adequate methods, facilities, and controls for receiving, preparing, processing, packing (including repacking), holding, and/or distributing FDA-regulated food to minimize the risk of introducing *L. mono* and other pathogenic organisms into the food, and to ensure that the food is not adulterated within the meaning of 21 U.S.C. § 342(a)(4). Such methods, facilities, and controls shall include, but not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants' Facility and all equipment therein suitable for use in receiving, preparing, processing, packing (including repacking), holding, and distributing articles of FDA-regulated food, and instituting standard sanitation operating procedures to ensure that the Facility and equipment therein are continuously maintained in a sanitary condition;

(2) Written procedures that identify the required preventive controls and manufacturing processes, consistent with the CGMP and PC Rule and designed to ensure that Defendants' manufacturing processes, monitoring procedures, and corrective actions protect against the contamination of food and food-contact surfaces and prevent insanitary conditions at Defendants' Facility;

(3) A written employee training program (in English and any other language necessary to convey the substance of the training to the employees), that includes, at a minimum, instructions on sanitary FDA-regulated food handling techniques and documentation that each employee has received such training. The employee training program shall include, at minimum, basic training for all employees on the importance of controls for bacterial pathogens including but not limited to, *L. mono* and their role in control strategies for bacterial pathogens, training for all employees who handle FDA-regulated food or work in areas where finished FDA-

regulated food is exposed to the environment to ensure that they understand how to prevent cross-contamination of food, and training for all employees who conduct cleaning and sanitation tasks to ensure that they understand the sanitation procedures necessary to minimize the risk of bacterial pathogens including but not limited to, *L. mono* in the Facility. Defendants' Expert(s) shall ensure that each employee has completed the program;

(4) A written program for environmental monitoring and testing of Defendants' Facility to ensure that organisms including but not limited to, *Listeria species* (*L. spp.*) are systematically controlled and that the pathogen *L. mono* does not occur in finished FDA-regulated food. Environmental monitoring shall include, but not be limited to, collecting swab samples from FDA-regulated food-contact surfaces, equipment, and other environmental sites throughout the Facility (where the raw ingredients, in-process, and finished articles of FDA-regulated foods are received, prepared, processed, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analyzing the environmental samples for the presence of *L. mono* and/or other pathogenic organisms. Sampling shall be conducted according to a method that specifies, at a minimum: how, where, and when to sample; and the number and frequency of samples to be collected. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) business days after receipt by Defendants;

(5) A written plan for effective remedial action, including, but not limited to intensified sanitation and intensified sampling measures, that Defendants shall implement if *L. mono* or any other pathogenic organism is detected during the sampling and testing conducted pursuant to paragraph 14(C)(4); and

(6) A sampling and testing plan appropriate for conducting finished

product testing in accordance with paragraph 15(B) below;

D. FDA approves, in writing, the Pathogen Control Program developed by the Expert(s) or chooses not to do so within 60 days;

E. Defendants:

(1) Assign continuing responsibility for implementing and monitoring the FDA-approved Pathogen Control Program to a person who, by reason of background, education, training, or experience, is qualified to maintain Defendants' Facility in a sanitary condition and implement all necessary remedial action, and Defendants provide such person with the authority and resources to achieve necessary remedial action;

(2) Make the FDA-approved Pathogen Control Program available and accessible (in English and any other language necessary to convey the substance of the document) to their officers, employees, and all other people who perform duties at Defendants' Facility;

(3) Successfully complete the FDA-approved employee training program;

(4) At their expense, clean and sanitize the Facility and equipment therein and make improvements to render the Facility and equipment suitable for receiving, preparing, processing, packing (including repacking), holding, and/or distributing articles of FDA-regulated food in accordance with this Decree, the Act, and the CGMP and PC Rule, and ensure that the Facility and equipment therein will be continuously maintained in a sanitary condition;

(5) Report to FDA in writing the actions they have taken to bring their operations in compliance with this Decree, the Act, and the CGMP and PC Rule, including:

i. Documentation that they have cleaned and sanitized the Facility and equipment therein and made improvements, thereby rendering the Facility and

equipment suitable for receiving, preparing, processing, packing (including repacking), holding, and distributing articles of FDA-regulated food, and documentation that they have conducted environmental monitoring and testing in accordance with the FDA-approved Pathogen Control Program;

ii. Specific measures that they have taken to address each of the deficiencies from the CGMP & PC Rule observed by FDA during all prior FDA inspections;

iii. A copy of the Pathogen Control Monitoring Program;

F. The Expert(s) conducts a comprehensive inspection of Defendants' Facility and the methods and controls used to receive, prepare, process, pack (including repack), hold, and/or distribute articles of FDA-regulated food to determine whether Defendants have effectively implemented all corrective actions and are operating in compliance with this Decree, the Act, and the CGMP and PC Rule. The Expert(s) shall verify, with supporting documentation, that:

(1) Defendants have corrected all of the violations of the CGMP & PC Rule observed by FDA during all prior FDA inspections since 2014; and

(2) Defendants' Facility and the methods and controls used to receive, prepare, process, pack (including repack), hold, and/or distribute articles of FDA-regulated food are, in the Expert(s)'s opinion, in compliance with this Decree, the Act, and the CGMP and PC Rule.

The Expert(s) shall submit a written report of all findings, with supporting documentation, to Defendants and FDA concurrently, within ten (10) business days after completing the inspection;

G. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and the CGMP and PC Rules, inspects Defendants' Facility,

including the building, sanitation-related systems, equipment, utensils, labeling, articles of FDA-regulated food, and relevant records contained therein;

H. Defendants pay all costs of inspections, investigations, supervision, analyses, sampling, testing, and reviews for FDA's oversight with respect to paragraph 14 at the rates set forth in paragraph 22; and

I. FDA has notified Defendants in writing that Defendants appear to be in compliance with the requirements set forth in this paragraph this Decree, the Act, and the CGMP and PC Rule. In no circumstance shall FDA's silence be construed as a substitution for written notification.

15. Upon resuming FDA-regulated food operations after complying with paragraph 13 and receiving FDA's written notification pursuant to paragraph 14(I), Defendants shall meet the following requirements:

A. Defendants shall continuously implement the Pathogen Control Program approved by FDA pursuant to paragraph 14(D). In the event that the Expert(s) or the Auditor(s) described in paragraph 15(C) (below) determines that the Pathogen Control Program requires revision, Defendants shall provide proposed changes to FDA in writing at least fourteen (14) business days prior to the planned implementation, and shall not implement their proposed changes unless and until FDA approves those changes in writing, or choses not to respond within 30 business days;

B. Defendants shall conduct finished product testing, in accordance with the finish product sampling and testing plan in the FDA-approved Pathogen Control Program, in the following manner:

(1) Immediately upon resumption of operations after the completion of the requirements of paragraph 14, Defendants shall test for *L. mono* in all lots of each food product for at least five consecutive production days using a testing method acceptable to FDA;

(2) After the completion of testing under paragraph 15(B)(1), Defendants shall test at least one lot of each food product per day for the next twenty (20) production days;

(3) After the completion of testing under paragraph 15(B)(2), Defendants shall test at least one lot of each food product per every five (5) production days for the next three (3) months; and

(4) After the completion of testing under paragraph 15(B)(3), Defendants shall test at least one lot of each food product per quarter thereafter;

C. Defendants shall retain an independent person or persons (the "Auditor(s)") who shall meet the criteria for, and may be the same person(s) as, the Expert(s) described in paragraphs 14(A), to conduct audit inspections of the Facility and the methods, processes, and controls used to receive, prepare, process, pack (including repack), hold, and/or distribute articles of FDA-regulated food, as follows:

(1) Within twenty (20) business days after Defendants resume their FDA-regulated operations, the Auditor(s) shall conduct a comprehensive audit inspection of Defendants' Facility and the methods and controls used to receive, prepare, process, pack (including repack), hold, and/or distribute articles of FDA-regulated food, to determine whether Defendants are operating in compliance with this Decree, the Act, and the CGMP and PC Rule, and to identify any deviations from those requirements;

(2) Thereafter, the Auditor shall conduct one audit inspection every three (3) months for one year, and then one audit inspection every six (6) months for the next two (2) years. Beginning in the fourth year after Defendants resume their FDA-regulated food operations, the Auditor(s) shall conduct audit inspections annually unless FDA informs Defendants in writing that more frequent audit inspections are required. During each audit inspection, the Auditor(s) shall verify that Defendants' Facility and the methods and controls that Defendants use to receive, prepare, process, pack (including repack), hold, and distribute articles of FDA-regulated food are in compliance with the requirements of this Decree, the Act, and the CGMP and PC Rule, and shall certify compliance in the Audit Report. As a part of every Audit Report (except the first one), the Auditor shall assess the adequacy of actions taken by Defendants to correct all previous audit observations indicating that Defendants are not in compliance with this Decree, the Act, or the CGMP and PC Rule. If the Audit Report contains any audit observations indicating that Defendants are not in compliance with this Decree, the Act, or the CGMP and PC Rule, Defendants shall make all necessary corrections within ten (10) business days after receipt of the Audit Report, unless FDA notifies Defendants in writing that a shorter time period is necessary; and

(3) The Auditor(s) shall submit Audit Reports documenting all findings to Defendants and FDA concurrently, within seven (7) business days after completing the audit inspection.

16. If, after notifying FDA of the name of the Laboratory retained to conduct sample analyses pursuant to paragraph 14(B), Defendants terminate or in any way alter their service contract with the Laboratory, Defendants shall notify FDA within five (5) business days after terminating or altering the service contract. If Defendants terminate their service contract,

Defendants shall provide a copy of the service contract with the new laboratory to FDA within five (5) business days after retaining the new laboratory.

17. Upon entry of this Decree, Defendants and their Associated Persons are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a), from directly or indirectly doing or causing any of the following acts:

A. Violating the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of FDA-regulated food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. Violating the Act, 21 U.S.C. § 331(k), by causing articles of FDA-regulated food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4);

C. Failing to implement and continuously maintain the requirements of this Decree.

18. If at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, report, or data submitted by Defendants, the Expert(s), Auditor(s), or any other information, that Defendants have failed to comply with any provision of this Decree, the Act, or the CGMP or PC Rule, or additional corrective actions are necessary to achieve compliance with this Decree, the Act, or the CGMP or PC Rule, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate action, including, but not limited to, ordering Defendants immediately to take one or more of the following actions:

A. Cease preparing, processing, packing (including repacking), and/or distributing any articles of FDA-regulated food;

B. Recall, at Defendants' expense, all articles of FDA-regulated food that have been distributed and/or are under the custody and control of Defendants or their agents, distributors, customers, or consumers;

C. Revise, modify, expand, or continue to submit any reports, plans, procedures, or other records prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Submit samples to a qualified laboratory for analysis;

F. Institute or reimplement any of the requirements set forth in this Decree;

G. Issue a safety alert; and/or

H. Take any other corrective actions as FDA deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, and the CGMP and PC Rule.

This remedy shall be separate and apart from, and in addition to, all other remedies available to FDA. Corporate Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel and subsistence expenses to implement and monitor the remedies set forth in this paragraph, at the rates specified in paragraph 22 of this Decree.

19. Upon receipt of any order issued by FDA pursuant to paragraph 18, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action as described in paragraph 18 shall continue until Defendants receive written

notification from FDA that Defendants appear to be in compliance with the Decree, the Act, and the CGMP and PC Rule, and that Defendants may resume operations. After a cessation of operations, and while determining whether Defendants are in compliance with this Decree, the Act, and the CGMP and PC Rule, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

20. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' operations and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and the CGMP and Rule. During such inspections, FDA representatives shall be permitted to: have immediate access to Defendants' places of business including, but not limited to all buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material therein; take photographs and make video recordings; take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material; and examine and copy all records relating to the receiving, preparing, processing, packing (including repacking), holding, and distributing of any and all of Defendants' food and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

21. If, at any time after entry of this Decree, FDA has determined that Defendants have resumed manufacturing, preparing, processing, packing, receiving, labeling, holding, and/or distributing FDA regulated food, Defendants shall immediately provide any information or records to FDA upon request regarding the receiving, preparing, processing, packing (including repacking), holding, and distributing of Defendants' FDA-regulated food. Defendants shall

maintain copies of their Pathogen Control Program, along with copies of all records required by that plan and this Decree, at the Facility and any other location(s) at or from which Defendants receive, prepare, process, pack (including repack), hold, and/or distribute articles of FDA-regulated food in a location where the records are readily available for inspection by FDA. Defendants shall retain all records referred to in this paragraph for at least three (3) years after the date the records are prepared.

22. If, at any time after entry of this Decree, FDA has determined that Defendants have resumed manufacturing, preparing, processing, packing, receiving, labeling, holding, and/or distributing FDA regulated food, or resumed any other FDA-regulated activity, with the exception of the limited activities noted in paragraph 12, Corporate Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, including all transportation and associated costs for FDA investigators and experts, at the standard rates prevailing at the time costs are incurred. Defendants shall make payment to FDA within twenty (20) business days after receiving an electronic invoice for payment, which shall be sent to floydjames@cox.net and idamcfield@cox.net. Defendants shall make payment through the Pay.gov electronic billing system, subject to all interest, fees, and penalties applicable to delinquent payments, in accordance with 31 U.S.C. § 3717 and 45 C.F.R. § 30. As of the date that this Decree is signed by the parties, these rates are: $116.47 per hour or fraction thereof per representative for inspection and investigative work; $139.61 per hour or fraction thereof per representative for analytical or review work; $0.67 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses, where necessary. In the event that the standard rates for FDA supervision of court-ordered compliance

are modified, these rates shall be increased or decreased without further order of the Court. Defendants shall notify FDA within fifteen (15) business day if the email address at which Defendants receive electronic invoices changes.

23. Within five (5) business days after entry of this Decree, Defendants shall prominently post a copy of this Decree (in English and any other language necessary to convey the substance of the Decree) in a conspicuous location in an employee common area at Defendants' Facility and shall ensure that the Decree remains posted for as long as the Decree remains in effect. Within ten (10) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

24. Within ten (10) business days after entry of this Decree, Defendants shall hold a general meeting or a series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree (in English and any other language necessary to convey the substance of the Decree). Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

25. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all of their Associated Persons. Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the

names, addresses, and positions of all Associated Persons who have received a copy of this Decree, and attaching a copy of the executed certified mail return receipts.

26. In the event that any Defendant becomes associated with any additional Associated Persons at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested), to such Associated Person(s). Within five (5) business days after each time that any of the Defendants becomes associated with any additional Associated Persons, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

27. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of their business that occurs after the entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, lease, sale, or any other change in the structure or identity of Freshy Food, LLC or Team Fresh & Go, LLC, or the assignment, lease, or sale of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising from this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

28. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its

attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

29. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

30. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall: be prominently marked "Decree Correspondence"; reference this civil action by case name and civil action number; and be submitted electronically to the Division Director, at orahafeast5firmresponses@fda.hhs.gov. If electronic submission is not possible, communications shall be addressed to the attention of Division Director, Food and Drug Administration, Office of Human and Animal Foods – East 5, 550 Main Street, Suite 4-930, Cincinnati, OH 45202.

31. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

32. This Court retains jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this 2nd day of July, 2024

HONORABLE JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

We hereby consent to the foregoing Decree:

FOR DEFENDANTS:

FLOYD D. JAMES [or IDA M. JAMES]
on behalf of FRESHY FOODS, LLC
as its co-owners

FLOYD D. JAMES [or IDA M. JAMES]
on behalf of TEAM FRESH & GO, LLC
as its co-owners

FLOYD D. JAMES
in his individual capacity

IDA M. JAMES
in her individual capacity

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