IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
RICHMOND DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	CIVIL ACTION NO. 3:16-cv-089
	)	
v.	)	
	)	
HENRY'S FARM, INC.,	)	CONSENT DECREE OF
a corporation, and	)	PERMANENT INJUNCTION
SOO C. PARK,	)	
an individual,	)	
	)	
	)	
Defendants.	)	

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Henry's Farm, Inc. ("Henry's Farm") and Soo C. Park (collectively, "Defendants"), and Defendants having appeared and consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest 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 over all parties to this action.

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

3. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4). Defendants also violate the Act, 21 U.S.C. § 331(k), by causing the adulteration of articles of food within the meaning of 21 U.S.C. § 342(a)(4), while such articles are held for sale after shipment of one or more components in interstate commerce. The articles of food are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth.

4. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly receiving, processing, manufacturing, preparing, packing, holding, and/or distributing, at or from their facility located at 5500 Fair Oaks Lane, Woodford, VA 22580-9635, and any other or new location at or from which Defendants receive, process, manufacture, prepare, pack, hold, and/or distribute food ("Defendants' facility"), any article of food, unless and until the following occur:

a. Defendants select and retain, at Defendants' expense, an independent laboratory (the "Laboratory") that has no personal or financial ties (aside from the terms of any agreement whereby Defendants retain the services of the Laboratory) to Defendants or their families. The Laboratory shall be qualified to collect product, spent irrigation water, and environmental samples from within Defendants' facility and analyze those samples for the

presence of *Listeria monocytogenes* ("*L. mono*") using a method that is acceptable to the United States Food and Drug Administration ("FDA"). Defendants shall notify FDA in writing immediately upon retaining such a Laboratory and shall provide FDA with a copy of the service contract. Such service contract shall contain provisions, deemed acceptable to FDA, for regular environmental and finished product sample collection and analyses, including how and where to sample, the number and frequency of samples to be collected, and the methods of analyses, in accordance with the Sanitation Control and Food Safety Plan discussed in Paragraph 4(c) below;

b. Defendants select and retain, at Defendants' expense, an independent expert(s) (the "Sanitation and Food Safety Expert") that has no personal or financial ties (aside from the terms of any agreement whereby Defendants retain the services of the Sanitation and Food Safety Expert) to Defendants or their families. The Sanitation and Food Safety Expert, by reason of background, education, training, and experience, shall be qualified to develop and ensure adequate implementation of a Sanitation Control and Food Safety Plan discussed in Paragraph 4(c) below and to inspect Defendants' facility and determine whether the methods, facilities, and controls operated and administered are in conformity with this Decree, the Act, and its implementing regulations. Defendants shall notify FDA in writing of the name and qualifications of the Sanitation and Food Safety Expert as soon as such expert is retained;

c. Defendants' Sanitation and Food Safety Expert, in consultation with the Laboratory and after reviewing of all FDA observations from May 2012 to present, develops an effective written Sanitation Control and Food Safety Plan covering Defendants' growing and manufacturing processes, cleaning and sanitizing operations, pest control, employee health and hygiene precautions, and facility construction and maintenance, including the facility's buildings

and sanitation-related systems (i.e., plumbing and sewage disposal), equipment, and utensils contained therein. The Sanitation Control and Food Safety Plan shall, at a minimum:

(i) Establish adequate methods, facilities, and controls for receiving, processing, manufacturing, preparing, packing, holding, and/or distributing articles of food to minimize the risk of introducing *L. mono*, other pathogenic organisms, and filth into Defendants' food, food-contact surfaces, and food-packaging materials, and to ensure that foods are not adulterated within the meaning of 21 U.S.C. § 342(a)(4). Such methods, facilities, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants' facility and all equipment therein suitable for use in receiving, processing, manufacturing, preparing, packing, holding, and distributing articles of food to prevent the articles of food from becoming adulterated, and instituting standard sanitation operating procedures ("SSOPs") as well as monitoring and record-keeping procedures to ensure that Defendants' facility and equipment therein are continuously maintained in a sanitary condition;

(ii) Ensure that seeds and beans used for sprouting are stored and transported in a manner that minimizes the likelihood that the seeds and beans will be contaminated with pathogens; that seeds and beans are stored in closed or covered containers in a clean and dry area dedicated to seed and bean storage; and that containers are positioned off the floor and away from walls to reduce the possibility of contamination by rodents and other pests, and to facilitate regular monitoring for pest problems;

(iii) Require that seeds and beans used for sprouting are treated with one or more scientifically valid treatments to reduce pathogens, and that Defendants monitor and control the parameters of the scientifically valid treatment(s);

(iv) Ensure that Defendants adhere to the requirements of 21 C.F.R.

Part 110, which sets forth good manufacturing practice ("GMP") in manufacturing, packaging, and holding human food;

(v) Establish a written employee training program that includes, at a minimum, instruction in sanitation control requirements for food-handling and manufacturing, and documentation that each employee, including part-time, temporary, or seasonal employees, has received such training. Defendants' Sanitation and Food Safety Expert shall test to confirm that each employee fully understands the substance of the employee training program;

(vi) Confirm that the cleaning and sanitizing are adequate through targeted environmental swabbing and appropriate microbial testing;

(vii) Require an effective program for environmental monitoring and facility testing to ensure that pathogenic organisms such as *L. mono* are not present within the facility. Environmental monitoring shall include, but not be limited to (a) collecting swab samples from food-contact and non-food-contact surfaces, equipment, other environmental sites throughout Defendants' facility where the raw ingredients, and in-process and finished articles of foods are received, processed, manufactured, prepared, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination, and (b) analyzing collected samples, in a manner and based on a schedule acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to this Paragraph are sent to FDA within two (2) calendar days of receipt by Defendants; and

(viii) Establish written procedures for remedial action should *Listeria species* ("*L. spp.*") *L. mono*, or any other pathogenic organism be detected;

d. Defendants assign continuing responsibility for implementing and monitoring the Sanitation Control and Food Safety Plan to a person(s), who, by reason of

background, education, training or experience, is competent to maintain Defendants' facility in a sanitary condition, coordinate with the Laboratory, and implement any necessary remedial action(s), and provide such person with the authority to achieve the necessary corrections;

e. FDA approves, in writing, the Sanitation Control and Food Safety Plan;

f. Defendants make written copies of the Sanitation Control and Food Safety Plan available and accessible to all their employees;

g. The Sanitation and Food Safety Expert conducts a comprehensive inspection of Defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein, to determine whether Defendants have adequately established and implemented the Sanitation Control and Food Safety Plan; have adequately addressed the FDA investigators' inspectional observations listed on each Form FDA-483 issued to Defendants since May 2012 and any other violations noted by any state government authority; and are operating in compliance with this Decree, the Act, and its implementing regulations. The Sanitation and Food Safety Expert shall submit all findings to Defendants and FDA concurrently within ten (10) calendar days of completion of the inspection;

h. Defendants report to FDA in writing regarding the actions they have taken to bring their operations into compliance with this Decree, the Act, and its implementing regulations, including:

(i) Producing documentation that Defendants have cleaned and sanitized Defendants' facility and equipment therein, and made improvements, thereby rendering the facility and equipment suitable for receiving, processing, manufacturing, preparing, packing, holding, and/or distributing articles of food, and documentation that Defendants have verified the

efficacy of the cleaning with one or more environmental tests, such as aerobic plate count or adenosine triphosphate swab;

(ii) Identifying specific measures that Defendants have taken to address each of the violations documented by FDA since May 2012; and

(iii) Providing FDA with a copy of the Sanitation Control and Food Plan;

i. Defendants develop and implement a system to facilitate tracing and recalling distributed products in the event of a violation or the potential for food-borne illness. Part of successful development and implementation shall mean that Defendants have tested their system to ensure that it is and will be adequate;

j. Within thirty (30) calendar days after entry of this Decree, Defendants shall destroy, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved by FDA in writing prior to implementation, all in-process and finished articles of food currently in their custody, control, or possession, if any, as of the date this Decree is signed by the parties. Defendants need not destroy any sprout seeds that will undergo an adequate sanitizing step before sprouting, if the seeds are adequately protected from pests. In the event that Defendants intend to retain any sprout seeds, within thirty (30) calendar days after entry of this Decree, Defendants shall provide to FDA documentation, the adequacy of which is to be determined by FDA, that such articles have been adequately protected from pests while being stored at Defendants' facility, and that any insanitary conditions previously identified by FDA, including but not limited to pest problems, have been corrected, such that Defendants' facility has been made sanitary and fit for the proper storage, handling, and manufacturing of articles of food;

k. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and all applicable regulations, conducts inspections of Defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein. FDA will initiate an inspection of Defendants' facility no later than forty (40) days after Defendants have demonstrated to FDA in writing that all of the requirements of paragraph 4 have been completed;

l. Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to Paragraph 4(a)-(k), at the rates set forth in Paragraph 8 below; and

m. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 4(a) through (l) of this Decree, the Act, and its implementing regulations.

5. Defendants shall not resume operations unless and until all the requirements of Paragraph 4 have been satisfied. Upon resuming operations after having satisfied these requirements, Defendants shall, in consultation with the Laboratory and the Sanitation and Food Safety Expert, continuously and effectively implement the following steps to prevent future contamination from *L. mono*, other pathogenic organisms, and/or filth in their food products and facility. Defendants shall:

a. Effectively implement on an ongoing basis the Sanitation Control and Food Safety Plan approved pursuant to Paragraph 4(e);

b. Conduct environmental monitoring and testing to ensure that the SSOPs continue to eliminate the *L. mono* hazard and are consistently being followed. Environmental monitoring shall include, but not be limited to (i) collecting swab samples from food-contact and

non-food-contact surfaces, equipment, other environmental sites throughout Defendants' facility where articles of food are received, processed, manufactured, prepared, packed, held, and/or distributed, up to and including final packaging, and common areas that could be reservoirs for cross-contamination, and (ii) analyzing such samples for the presence of *L. spp.* Environmental testing for *L. spp.* shall be performed by the Laboratory in accordance with timetables and methods that Defendants submit in writing for approval by FDA in writing before testing begins. Defendants shall ensure that the results of all testing conducted pursuant to this Paragraph are forwarded to FDA within two (2) calendar days after receipt by Defendants. Defendants' environmental testing must include, at a minimum, all of the following:

(i) If a food-contact or non-food-contact surface is found to be positive for *L. spp.* during routine testing, intensified sampling must be done as soon as possible, in conjunction with intensified sanitation measures. Intensified sampling requires that three (3) samples per day must be collected and analyzed until at least nine (9) consecutive samples (three (3) days of intensified sampling) have been taken and are negative for *L. spp.* from the site where the *L. spp.* was identified. After nine (9) consecutive samples are tested and found to be negative, that site may be subject to routine sampling; and

(ii) Any *L. spp.* isolate from a food-contact surface must be tested further to determine if it is *L. mono*. In addition, all food products that have come in contact with a site that tests positive for the general strain *L. spp.* must be placed on hold pending laboratory test results of those food products and further testing of the *L. spp.* isolate from the food-contact surface. The food products can be released only if laboratory test results for the food products are negative for *L. mono* and the *L. spp.* isolate from the food-contact surface is not *L. mono*; if the laboratory test results for the food products and/or *L. spp.* isolate from food-contact surface

are positive for *L. mono*, all implicated food products manufactured must be destroyed at Defendants' expense, under FDA's supervision, and according to a written destruction plan submitted by Defendants and approved in writing by FDA prior to implementation. Implicated food product is product that was manufactured on the equipment that yielded *L. mono* from the time of the last cleaning and sanitizing prior to sampling up to the time of cleaning and sanitizing following the sampling

c. Conduct microbiological testing of spent irrigation water from each production lot to ensure that contaminated product is not distributed. Defendants must obtain the test results before shipping product and shall not ship any product from a production lot where contamination is found; and

d. Finished product testing must be conducted in the following manner:

(i) Defendants shall test for *L. mono* in all lots of each food product for at least five (5) consecutive production days using a testing method approved in writing in advance by FDA;

(ii) After the completion of testing under Paragraph 5(d)(i), Defendants shall test at least one lot of each food product per day for the next twenty (20) production days;

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

(iv) After the completion of testing under Paragraph 5(d)(iii), Defendants shall test at least one lot of each food product per month thereafter.

If any laboratory test completed pursuant to Paragraphs 5(d)(i)-(iv) shows the presence of *L. mono* in any article of food, then Defendants must immediately cease production and notify FDA that production has ceased. Defendants shall also destroy, at Defendants' expense, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved in writing by FDA prior to implementation, all food products manufactured from the time the laboratory sample(s) testing positive for *L. mono* was collected. Defendants may resume production only after they have determined and corrected the cause of the contamination and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Decree, the Act, and its implementing regulations. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under this Paragraph anew. Defendants shall ensure that the results of all testing conducted under this Paragraph are forwarded to FDA within two (2) calendar days after receipt by Defendants.

6. If, after notifying FDA of the name of the laboratory retained to conduct sample collection and analyses pursuant to Paragraph 4(a), Defendants terminate or in any way alter their service contract with the laboratory, Defendants shall notify FDA within five (5) calendar days. If Defendants terminate their service contract, Defendants shall provide FDA a copy of the service contract with the new laboratory within five (5) calendar days of execution.

7. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles

of food, containers, and packaging material; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, processing, manufacturing, preparing, packing, holding, and/or distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

8. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $89.35 per hour and fraction thereof per representative for inspection work; $107.09 per hour or fraction thereof per representative for analytical or review work; .575 cents 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 or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

9. Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who have received notice of this Decree, are permanently restrained

and enjoined pursuant to the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

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

b. violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such articles are held for sale after shipment of one or more components in interstate commerce; and/or

c. results in the failure to implement and continuously maintain the requirements of this Decree.

10. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, or any other information, that Defendants have failed to comply with any provision of this Decree, the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate action immediately, including, but not limited to, one or more of the following:

a. Cease receiving, processing, manufacturing, preparing, packing, holding, and/or distributing any articles of food, until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations, and that Defendants may resume operations;

b. Recall all articles of food that have been distributed and/or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

c. Submit samples of raw ingredients, in-process or finished articles of food, containers, and packaging materials to a qualified laboratory to determine whether they are contaminated with chemicals, toxins, microorganisms, and/or filth; and/or

d. 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 its implementing regulations, including, but not limited to, requiring that Defendants re-implement or re-institute any of the requirements of this Decree.

11. The provisions of Paragraph 10 shall be apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in Paragraph 8 of this Decree.

12. Upon receipt of an FDA order described in Paragraph 10, Defendants shall immediately and fully comply with the terms of the order, and shall continue to comply with such terms, until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. After a cessation of operations, and while determining whether Defendants are in compliance with this Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

13. If any Defendant fails to comply with the provisions of this Decree, the Act, and/or its implementing regulations, then Defendants shall pay to the United States of America liquidated damages in the sum of two thousand dollars ($2,000.00) for each day that the Defendants fail to comply with this Decree; an additional sum of 250 hundred dollars ($250.00)

in liquidated damages per day for each violation of this Decree, the Act, and/or its implementing regulations; and an additional sum equal to twice the retail value of each shipment of adulterated food. Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

14. If any Defendants violate this Decree and is found in civil or criminal contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to contempt proceedings.

15. 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, if contested, shall be reviewed by this 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.

16. Within ten (10) calendar days after entry of this Decree, Defendants shall:

a. provide a copy of this Decree by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates);

b. prominently post a copy of this Decree in an employee common area at Defendants' facility, and ensure that this Decree remains posted so long as it remains in effect; and

c. hold a meeting for their employees, at which Defendants shall describe the terms and obligations of this Decree.

Within twenty (20) calendar days after entry of this Decree, Defendants shall provide FDA with an affidavit of compliance with this paragraph, stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

17. In the event that any Defendant becomes associated with any additional directors, officers, agents, representative, employees, attorneys, successors, assigns, or any additional persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such persons. Within ten (10) calendar days after each instance that Defendant becomes associated with any individual persons, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this Paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this Paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this Paragraph, Defendants shall provide such information or documentation to FDA.

18. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business, including reorganization,

relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least ten (10) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this Paragraph within ten (10) calendar days of providing a copy of this Decree to a prospective successor or assign.

19. Defendants shall address all communications required under this Decree to the Director of Compliance, District Office, United States Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, MD 21215, shall prominently mark the envelope as "DECREE CORRESPONDENCE," and shall reference this civil action by case name and civil action number.

20. No sooner than five (5) years after entry of this Decree, Defendants may petition FDA for leave to ask this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with this Decree, the Act, and its implementing regulations for at least five (5) years, Plaintiff will not oppose the petition, and Defendants may request the Court to grant such relief.

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

SO ORDERED this 3rd day of March, 2016.

/s/
Henry E. Hudson
United States District Judge

We hereby consent to the entry of the forgoing Decree:

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and on behalf of Henry's Farm, Inc.

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