

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW YORK

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U.S. DISTRICT COURT E.D.N.Y.  
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LONG ISLAND OFFICE

CV23 9073

Civil No. \_\_\_\_\_

**BROWN, J.**

**SHIELDS, M.J.**

UNITED STATES OF AMERICA, )  
 )  
 Plaintiff, )  
 )  
 v. )  
 )  
 TOTAL BODY NUTRITION LLC and )  
 TBN Labs LLC, New York corporations, and )  
 LOUD MUSCLE SCIENCE, LLC, a Delaware )  
 corporation, )  
 )  
 and )  
 )  
 MOHAMMED ISLAM, individual, )  
 )  
 Defendants. )  
 )  
 \_\_\_\_\_ )

**CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction against Total Body Nutrition LLC, TBN Labs LLC, and Loud Muscle Science, LLC, corporations (collectively, "TBN"), and Mohammed Islam, an individual (collectively, "Defendants"), and Defendants having appeared and consented to entry of this 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 as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. § 332 and its inherent equitable authority, and has personal jurisdiction over 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 to be introduced or delivered for introduction into interstate commerce, dietary supplements as defined by 21 U.S.C. § 321(ff), that are:

A. Adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of the current good manufacturing practice regulations for dietary supplements set forth in 21 C.F.R. Part 111 (“Dietary Supplement CGMP”); and

B. Misbranded within the meaning of 21 U.S.C. §§ 343(i)(2), (k), (q)(5)(F), (s)(2)(C), and/or (y), because for all or some of Defendants’ dietary supplements, the label fails to provide the common or usual name of individual ingredients; the labeling fails to state the name of any artificial coloring contained in the product; the label or labeling fails to present the nutrition information in a Supplement Facts panel; the label or labeling fails to identify the part of the plant from which each botanical dietary ingredient is derived; and/or the label fails to include a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event with the dietary supplement.

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing dietary supplements that Defendants hold for sale after shipment of one or more components in interstate commerce to become:

A. Adulterated within the meaning of 21 U.S.C. § 342(g)(1), because they have been prepared, packed, or held under conditions that do not meet Dietary Supplement CGMP; and

B. Misbranded within the meaning of 21 U.S.C. §§ 343(i)(2), (k), (q)(5)(F), (s)(2)(C), and/or (y).

5. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise (collectively, “Associated Persons”), are hereby subject to the following requirements:

A. Within twenty (20) calendar days of entry of this Decree, Defendants shall retain, at Defendants’ expense, an independent person (the “CGMP Expert”) who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to inspect Defendants’ facility located at 300 Oser Avenue, Hauppauge, New York 11788, or any other location(s) at which Defendants now or in the future directly or indirectly receive, manufacture, prepare, process, pack, repack, label, hold, and/or distribute dietary supplements (hereafter, “Defendants’ Facility” or “the Facility”) to determine whether the facilities, methods, processes, and controls are operated and administered in conformity with Dietary Supplement CGMP (21 C.F.R. Part 111). Defendants shall notify FDA in writing of the identity and qualifications of the CGMP Expert within three (3) calendar days after retaining such CGMP Expert;

B. Within thirty (30) calendar days of entry of the Decree, the CGMP Expert shall perform and complete a comprehensive in-person inspection of the Facility and the methods, processes, and controls used to receive, manufacture, prepare, process, pack, repack, label, hold, and/or distribute dietary supplements and certify in writing to FDA: (a) that he or she has inspected the Facility, methods, processes, and controls; (b) whether all deviations from Dietary Supplement CGMP that have been brought to Defendants’ attention by FDA, the CGMP Expert, and any other source have been corrected; and (c) whether the Facility and the methods,

processes, and controls used to receive, manufacture, prepare, process, pack, repack, label, hold, and/or distribute dietary supplements, are, in the CGMP Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The CGMP Expert's report of the inspection shall be submitted to Defendants and FDA concurrently, within thirty (30) calendar days of completion of the inspection, and shall include, but not be limited to, a determination whether Defendants have created and implemented a system of methods, processes, and controls to ensure that they, at a minimum:

i. Establish product specifications for the identity, purity, strength, and composition of the finished batches of dietary supplements that Defendants manufacture, *see* 21 C.F.R. § 111.70(e);

ii. Verify that finished batches of dietary supplements that Defendants manufacture meet product specifications for identity, purity, strength, composition, and for limits on those types of contamination that may lead to adulteration of the finished batches, *see* 21 C.F.R. § 111.75(c);

iii. Conduct at least one appropriate test or examination to verify the identity of a dietary ingredient prior to its use, *see* 21 C.F.R. § 111.75(a)(1)(i);

iv. For each component used in the manufacture of a dietary supplement, establish specifications to ensure that specifications for the identity of dietary supplements manufactured using the components are met, *see* 21 C.F.R. § 111.70(b)(1);

v. Prepare batch production records for dietary supplements that Defendants manufacture that include complete information relating to the production and control of each batch, *see* 21 C.F.R. § 111.255(b);

- vi. Prepare batch production records that accurately adhere to the appropriate master manufacturing record, *see* 21 C.F.R. § 111.255(c);
- vii. Establish and follow written procedures for maintaining, cleaning, and sanitizing equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements, *see* 21 C.F.R. § 111.25(c);
- viii. Ensure that quality control personnel reject a dietary supplement for which a specification was not met, *see* 21 C.F.R. § 111.77(a);
- ix. Prepare and follow written procedures for preventing microbial contamination from sick or infected personnel, hygienic practices, and determining personnel qualification requirements, *see* 21 C.F.R. § 111.14(b)(1);
- x. Prepare and follow adequate written procedures for pest control, *see* 21 C.F.R. § 111.23(b); and
- xi. Collect and hold reserve samples of packaged and labeled dietary supplements distributed by Defendants, *see* 21 C.F.R. § 111.83(a);

C. Within twenty (20) calendar days of entry of the Decree, Defendants shall retain, at Defendants' expense, an independent person (the "Labeling Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to review dietary supplement product labels and labeling to determine whether Defendants' product labeling complies with 21 U.S.C. § 343 and applicable regulations. The Labeling Expert may be the same person identified in Paragraph 5(B) as the CGMP Expert. Defendants shall notify FDA in writing of the identity and qualifications of the Labeling Expert within three (3) calendar days after retaining such Labeling Expert;

D. Within thirty (30) calendar days of entry of the Decree, the Labeling Expert shall perform and complete a comprehensive review of Defendants' product labels and labeling and certify in writing to FDA: (1) that he or she has reviewed Defendants' product labels and labeling; (2) whether all labeling violations brought to Defendants' attention by FDA, the Labeling Expert, and any other source have been corrected; and (3) whether Defendants' products are, in the Labeling Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The Labeling Expert shall prepare a detailed report of this review, which shall be submitted to Defendants and FDA concurrently, within thirty (30) calendar days of completion of this review, that shall include, but not be limited to, a determination whether Defendants have implemented procedures that are adequate to ensure that their product labeling complies with 21 U.S.C. § 343 and applicable regulations;

E. Should the CGMP Expert or the Labeling Expert identify any deficiencies in their reports as described in Paragraphs 5(B) and (D),

i. Within thirty (30) calendar days of receipt of the CGMP Expert's or Labeling Expert's report, Defendants shall report in writing to FDA and the appropriate Expert the actions they have taken to correct all such deficiencies;

ii. Within ten (10) calendar days of Defendants' report as described in Paragraph 5(E)(i), the CGMP Expert shall certify in writing to FDA, based on his or her further review and/or inspection(s), whether Defendants' Facility, methods, processes, and controls used to receive, manufacture, prepare, process, pack, repack, label, hold, and/or distribute dietary supplements are operated in conformity with Dietary Supplement CGMP, the Act, and this Decree;

iii. Within ten (10) calendar days of Defendants' report as described in Paragraph 5(E)(i), the Labeling Expert shall certify in writing to FDA, based on his or her further review and/or inspection(s), whether Defendants have updated their labels and/or labeling to ensure that Defendants' dietary supplements are in compliance with this Decree, the Act, and its implementing regulations; and

iv. FDA will notify Defendants in writing of its evaluation of such submissions;

F. Defendants shall destroy, under FDA's supervision and in accordance with the procedures provided in Paragraph 6, all dietary supplements that are in Defendants' possession, custody, or control that are adulterated because they were not received, manufactured, prepared, processed, packed, repacked, labeled, held, and/or distributed by Defendants in compliance with the Act and its implementing regulations;

G. After receipt of the CGMP Expert's certification and report (as described in Paragraph 5(B)) and the Labeling Expert's certification and report (as described in Paragraph 5(D)), FDA, without notice and as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and all applicable regulations, may inspect Defendants' Facility; and

H. FDA will notify Defendants in writing whether they appear to be in compliance with the requirements set forth in Paragraphs 5(A)–(G) of this Decree, the Act, and its implementing regulations. In no circumstance shall FDA's silence be construed as a substitute for written notification.

6. Within twenty (20) calendar days after entry of this Decree, Defendants, under FDA's supervision and to FDA's satisfaction, shall destroy all dietary supplements that are in

Defendants' possession, custody, or control that are adulterated because they were not received, manufactured, prepared, processed, packed, repacked, labeled, held, and/or distributed by Defendants in compliance with the Act and its implementing regulations. Prior to destruction, Defendants must submit a written destruction plan to FDA and no destruction can take place until the destruction plan has been approved by FDA in writing. Under no circumstances shall FDA's silence be construed as a substitute for written notification. Defendants shall not dispose of any dietary supplements in a manner contrary to the provisions of the Act, any other federal law, or the laws of any state or territory in which the dietary supplements are disposed. Defendants shall bear the cost of the destruction and FDA supervision at the rates specified in Paragraph 13.

7. After Defendants have complied with Paragraph 5(A)–(G) and received FDA's written notification pursuant to Paragraph 5(H), Defendants shall retain an independent person or persons who shall meet the criteria described in Paragraph 5(B) and (D) (the "Auditor") to conduct audit inspections of Defendants' Facility no less frequently than once every six (6) months for a period of no less than five (5) years. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to Paragraph 5(H). The Auditor may be the same person or persons retained as an Expert described in Paragraph 5(B) and (D).

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether or not Defendants are operating in compliance with Dietary Supplement CGMP, the dietary supplement labeling requirements, this Decree, the Act, and its implementing regulations, and identifying in detail any deviations from the foregoing ("Audit Report Observations").



B. Each Audit Report shall contain a written certification that the Auditor: (1) has personally inspected Defendants' Facility and operations in-person and reviewed all product labels and labeling; and (2) personally certifies whether or not Defendants' dietary supplements are in compliance with Dietary Supplement CGMP, the dietary supplement labeling requirements, and the requirements of this Decree, the Act, and its implementing regulations.

C. As a part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA, at the address provided in Paragraph 22, by courier service or overnight delivery service, no later than fifteen (15) calendar days after the date the audit inspection is completed. In addition, Defendants shall maintain all of their Audit Reports and all of their underlying data in separate files at Defendants' Facility and shall promptly make the Audit Reports available to FDA upon request.

D. If an Audit Report contains any observations indicating that Defendants' dietary supplements are not in compliance with Dietary Supplement CGMP, the dietary supplement labeling requirements, this Decree, the Act, or its implementing regulations, Defendants shall, within fifteen (15) calendar days after receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations may take longer than fifteen (15) calendar days, Defendants shall, within ten (10) calendar days after receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be

construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule.

E. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within thirty (30) calendar days after the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in an Audit Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Defendants shall ensure that within five (5) calendar days after beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

8. Defendants and all Associated Persons are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing to be introduced or delivered for introduction into interstate commerce, dietary supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343;

B. Violating 21 U.S.C. § 331(k), by causing dietary supplements to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343, while such articles are held for sale after shipment of one or more of their components in interstate commerce; and

C. Failing to implement and continuously maintain the requirements of this Decree, including, but not limited to, failing to comply with Dietary Supplement CGMP and the dietary supplement labeling provisions of the Act and its implementing regulations.

9. If, at any time after this Decree has been entered, FDA determines, based on a review of inspection results; product labels or labeling; a report prepared by Defendants' Experts or the Auditor; or any other information, that Defendants have failed to comply with any provision of this Decree, have violated 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 corrective actions, including, but not limited to, ordering Defendants to immediately:

A. Cease receiving, manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any or all dietary supplements;

B. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

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

D. Recall, at Defendants' expense, any dietary supplement products that, in FDA's judgment, are or may be adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

E. Submit additional samples to a qualified laboratory for analysis;

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

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

H. Issue a safety alert; and/or

I. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with this Decree, the Act, or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

10. The following process and procedures shall apply in the event that FDA issues an order under Paragraph 9.

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such an order, Defendants shall notify FDA in writing either that (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with the FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification, and thereafter, in writing, affirm, modify, or withdraw its order as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice or affirmation shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the terms of the order (as modified, if applicable), and may, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement and comply with FDA's order, unless

and until the Court stays, reverses, or modifies FDA's order. Any judicial review of FDA's order under this Paragraph shall be made pursuant to Paragraph 20.

D. The process and procedures set forth in Paragraph A-C above shall not apply to any order issued pursuant to Paragraph 9 if such order states that, in FDA's judgment, the matter raises a significant public health concern. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's order. Any judicial review of FDA's order under this Paragraph shall be made pursuant to Paragraph 20.

11. Any cessation of operations or other action described in Paragraph 9 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. Upon Defendants' written request to resume operations following cessation directed by FDA under Paragraph 9, as soon as practicable, FDA will determine whether Defendants appear to be in such compliance, and if they are, issue to Defendants a written notification permitting, as appropriate, resumption of operations. Under no circumstance shall FDA's silence be construed as a substitute for written notification. 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 Paragraph 9, at the rates specified in Paragraph 13.

12. FDA representatives shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms

of this Decree. During such inspections, FDA representatives shall be permitted immediate access to buildings, equipment, in-process and finished materials, containers, and Defendants' product labels and labeling; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, and Defendants' product labels and labeling; and to examine and copy all product labels and labeling, and all records relating to the receipt, manufacture, preparation, processing, packing, repacking, labeling, holding, and/or distribution of any and all of Defendants' products. 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 conduct inspections under the Act, 21 U.S.C. § 374.

13. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree, including the travel incurred by specialized investigatory and expert personnel, 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: \$110.59 per hour or fraction thereof per representative for inspection and investigative work; \$132.56 per hour or fraction thereof per representative for analytical or review work; \$0.65 (plus tolls) per mile for travel expenses 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 applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court. Defendants shall make payment in full to FDA within twenty (20) calendar days after receiving written notification from FDA of the costs.

14. Within five (5) calendar days after entry of this Decree, Defendants shall post a copy of this Decree in a conspicuous location in a common area at Defendants' Facility and ensure the Decree remains posted for as long as the Decree remains in effect. Within ten (10) calendar 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.

15. Within ten (10) calendar days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all employees, at which they shall describe the terms and obligations of this Decree. Within fifteen (15) calendar 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 minutes from the meeting(s) held pursuant to this Paragraph.

16. Within ten (10) calendar days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or electronic mail to each and all Associated Persons. Within twenty (20) calendar 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 electronic notifications.

17. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or electronic mail to such Associated Person(s). Within fifteen (15) calendar days after each time that any of the Defendants becomes

associated with any additional Associated Person, 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 electronic notifications.

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

19. 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.

20. 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.

21. If any deadline in this Decree falls on a weekend or federal holiday, the deadline is continued to the next business day.

22. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Consent Decree Correspondence" and addressed to Division Director, Office of Human and Animal Food Operations East 1 (HAFE 1), New York District Office, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433, and via email at [orahafeast1firmresponses@fda.hhs.gov](mailto:orahafeast1firmresponses@fda.hhs.gov), and shall reference this civil action by case name and civil action number.

23. No sooner than sixty (60) months 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 sixty (60) months, the United States will not oppose the petition, and Defendants may request the Court to grant such relief.

24. This Court retains jurisdiction over this action and the parties thereto 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, this 13<sup>th</sup> day of December, 2023.

/s/Gary R. Brown  
UNITED STATES DISTRICT JUDGE

Entry consented to:

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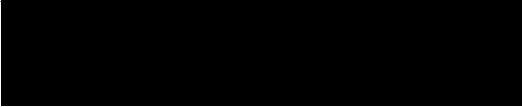
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and LOUD MUSCLE SCIENCE, LLC

  
MOHAMMED ISLAM  
Individually

  
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