BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
U.S. Department of Justice
Civil Division
JONATHAN F. OLIN
Deputy Assistant Attorney General
MICHAEL S. BLUME
Director
Consumer Protection Branch
JILL FURMAN
Deputy Director

DANIEL ZYTNICK
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street, NW, Suite 6400 South
Washington, DC 20530
Telephone: (202) 598-8337
Facsimile: (202) 514-8742
Email: Daniel.E.Zytnick@usdoj.gov

JS-6

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. CLIFFORD WOODS LLC, a limited liability company d/b/a VIBRANT LIFE, and CLIFFORD WOODS, an individual, Defendants.	No. CV15-8889-DDP-JEM **CONSENT DECREE OF PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF**

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Injunction and Other Equitable Relief against Clifford Woods, LLC, a limited liability company doing business as Vibrant Life, and Clifford Woods, 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.

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"), and the civil fraud injunction statute, 18 U.S.C. § 1345 ("Section 1345").

3. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved under 21 U.S.C. § 355 nor exempt from approval.

4. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because their labeling fails to bear adequate directions for use.

5. Defendants violate 18 U.S.C. §§ 1341 and 1343 by promoting, selling, and receiving money in exchange for products to cure, mitigate, treat, or prevent a disease despite the absence of well-controlled clinical studies or any other credible scientific substantiation to support those representations, and by (1) doing so using the United States mail and/or a private or commercial interstate carrier and (2) transmitting writings by wire in interstate commerce for the purpose of executing such scheme or artifice.

6. This Court has authority pursuant to 21 U.S.C. § 332(a), and inherent authority, to order injunctive and other equitable relief remedying the unlawful activities described in paragraphs 3 and 4. This Court has authority pursuant to 18

U.S.C. § 1345, and inherent authority, to order injunctive and other equitable relief remedying the unlawful activities described in paragraph 5.

7. Defendant Clifford Woods LLC is a California company that does business as Vibrant Life, and sells and distributes dietary supplements under the brand name Vibrant Life. Defendant Clifford Woods owns and operates Clifford Woods LLC and serves as executive director of Vibrant Life.

8. The Food and Drug Administration ("FDA") sent a Warning Letter, dated August 7, 2013, to Defendant Woods (operating at that time as Vibrant Life or Vibrant Life Vitamins) concerning products and claims found on Defendants' websites. The Warning Letter advised Defendant Woods that the products were new drugs, which may not be legally introduced or delivered for introduction into interstate commerce without prior FDA approval. The Warning Letter further advised Defendant Woods that the products were misbranded drugs, whose introduction or delivery into interstate commerce also violates the Act.

9. Upon entry of this Decree, Defendants represent to the Court that they are not directly or indirectly engaged in processing, packing, repacking, labeling, holding, or distributing any article of food (including but not limited to dietary supplements and their components) and/or any article of drug.

10. If Defendants later intend to resume operation of Vibrant Life or any other enterprise engaged in manufacturing, processing, packing, labeling, holding, or distributing any article of food (including but not limited to dietary supplements and their components) and/or any article of drug, Defendants must notify FDA in writing at least ninety (90) days in advance of resuming operations and must comply with Paragraph 13 of this Decree.

11. Defendants' notice under Paragraph 10 shall identify the type(s) of products that Defendants intend to process, pack, repack, label, hold, and/or distribute, and the location(s) at which Defendants intend to resume operations.

12. Defendants shall not resume operations until the conditions in Paragraphs 13(A)-(B) and 13(D) are satisfied, and Defendants have received written notice from FDA, as required by Paragraph 13(E), and then Defendants shall resume such operations only to the extent authorized in FDA's written notice.

PROHIBITED CONDUCT

13. 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 or entities 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 from directly or indirectly introducing and delivering for introduction into interstate commerce, causing to be introduced and delivered for introduction into interstate commerce, and holding for sale after shipment in interstate commerce, any product unless and until:

A. Defendants have in effect with respect to the product a new drug application or abbreviated new drug application approved pursuant to 21 U.S.C. § 355(c) or (j), or an investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i), or the following requirements are met:

1. Defendants remove from their product labels, labeling, promotional material, websites (including but not limited to arthritisinformation.net, bulkmsm.com, chelationtherapyonline.com, heart-disease-bypass-surgery.com, oralchelation.com, vibrantlifemsm.com, and vibrantlifenews.com), branded Facebook pages, and any other media (a) all representations that their products or the ingredients in their products cure, mitigate, treat, or prevent disease, and all representations that otherwise cause any of their products to be a drug within the meaning of the Act, and (b) all links and

references, direct or indirect, to other websites or other sources that contain representations that their products or the ingredients in their products cure, mitigate, treat, or prevent disease, and representations that otherwise cause any of their products to be a drug within the meaning of the Act;

2. Defendants provide notice, by letter or electronic mail, to all persons who are or have been involved in the promotion, sale, distribution, or use of Defendants' Taheebo Life Tea, Life Glow Plus, Germanium, Organic Sulfur ("MSM"), or any other product labeled as containing organic sulfur or methyl sulfonyl methane, informing those persons that, pursuant to an order of this Court, those products should not have been and can no longer be promoted, sold, or distributed for use in the cure, mitigation, treatment, or prevention of disease and that continued promotion, sale, or distribution of the products for the cure, mitigation, treatment, or prevention of disease is a violation of the Act. Prior to distribution, the notification shall be submitted to, and approved in writing by, FDA. After completing distribution of the notification required by this paragraph, Defendants shall provide FDA with 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 and addresses of each recipient who has received a copy of the notification.

3. Defendants 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 Defendants' product labels, labeling, promotional material, websites (including but not limited to arthritisinformation.net, bulkmsm.com, chelationtherapyonline.com, heart-disease-bypass-surgery.com, oralchelation.com, vibrantlifemsm.com, and vibrantlifenews.com), branded Facebook pages, and other media to assess compliance with the Act. Defendants shall notify FDA in

writing of the identity and qualifications of the Labeling Expert within three (3) business days of retaining such expert; and

4. The Labeling Expert provides to FDA a written certification that, based on a comprehensive review, Defendants' product labels, labeling, promotional material, websites (including but not limited to arthritisinformation.net, bulkmsm.com, chelationtherapyonline.com, heart-disease-bypass-surgery.com, oralchelation.com, vibrantlifemsm.com, and vibrantlifenews.com), branded Facebook pages, and other media comply with the Act, and do not contain, or link or refer to other websites or other sources that contain, representations that their products or the ingredients in their products cure, mitigate, treat, or prevent disease, or representations that otherwise cause any product to be a drug within the meaning of the Act. The written certification described in this paragraph shall include a list of all of Defendants' websites, including social media pages and online marketplace postings. The written certification shall also contain a detailed report of the Labeling Expert's review and include, but not be limited to, a determination that Defendants have implemented procedures that are adequate to ensure that their claims do not cause any of their products to be a drug within the meaning of 21 U.S.C. § 321(g)(1) unless and until the product is the subject of an approved new drug application or abbreviated new drug application, or is exempt from approval under an investigational new drug application, 21 U.S.C. §§ 355(a), (b), (i), and (j);

B. Defendants report to FDA in writing the actions they have taken to ensure that their claims do not cause any of their products to be a drug within the meaning of 21 U.S.C. § 321(g)(1) unless and until the product is the subject of an approved new drug application or abbreviated new drug application, or is exempt from approval under an investigational new drug application, 21 U.S.C. §§ 355(a), (b), (i), and (j);

C. As and when FDA deems necessary, FDA representatives inspect Defendants' operations, including the buildings, equipment, products, labeling, and all relevant records contained therein, to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Decree;

D. Defendants have paid all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews with respect to paragraph 13, at the rates set forth in paragraph 21; and

E. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 13(A)-(B) and (D) of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

14. Upon entry of this Decree, and after receiving FDA's written notification pursuant to paragraph 13(E), Defendants and 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(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval;

B. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

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

COMPLIANCE REQUIREMENTS

15. Upon resuming operations after complying with paragraphs 13(A)-(B) and (D), and receiving FDA's written notification pursuant to paragraph 13(E), the following requirements shall be met:

A. Defendants shall notify FDA in writing, at least fourteen (14) days before the creation of a new website or link or reference, direct or indirect, to another website or other source that conveys information about Defendants' products or the ingredients in their products; and

B. Defendants shall retain an independent person or persons (the "Auditor") who shall meet the criteria for, and may be the same person(s) as, the Labeling Expert described in paragraph 13(A)(3), to conduct audits of Defendants' product labels, labeling, promotional material, websites (including but not limited to arthritisinformation.net, bulkmsm.com, chelationtherapyonline.com, heart-disease-bypass-surgery.com, oralchelation.com, vibrantlifemsm.com, and vibrantlifenews.com), branded Facebook pages, and other media to assess compliance with the Act. Thereafter:

1. The Auditor shall conduct audit inspections no less frequently than once every six (6) months for a period of no less than five (5) years and then at least once every year thereafter. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to paragraph 13(E);

2. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with this Decree, the Act, and its implementing regulations and identifying any deviations from such requirements ("Audit Report Observations"). 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 Report Observations. The Audit Reports shall be delivered

contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than seven (7) days after the audit inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate files at Defendants' facility and shall promptly make the Audit Reports available to FDA upon request; and

3. If an Audit Report contains any Audit Report Observations, Defendants shall, within fourteen (14) 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 Audit Report Observations will take longer than fourteen (14) days, Defendants shall, within seven (7) 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. Immediately upon completion of all corrections, Defendants shall submit documentation of their corrections to the Auditor. Within twenty-eight (28) days after the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, or, if there is an FDA-approved Audit Correction Schedule, within the time period provided therein, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within seven (7) 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.

16. If Defendants engage in manufacturing, processing, packing, labeling, holding or distributing any drug or dietary supplement, Defendants will comply with the Act and its implementing regulations.

17. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, review, the analysis of a sample, a report, or data prepared or submitted by Defendants, the Labeling Expert, Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, Defendants have violated the Act or its implementing regulations, or 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 action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, processing, packing, repacking, labeling, holding, or distributing any and all products;

B. Recall, at Defendants' expense, any and all products;

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

F. Issue a safety alert; and/or

G. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants 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.

18. Upon receipt of any order issued by FDA pursuant to paragraph 17, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 17 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. 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 17, at the rates specified in paragraph 21.

19. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' operations and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and all applicable regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to the Defendants' places of business including, but not limited to all buildings, equipment, in-process materials, finished products, containers, packaging material, labeling, and other material therein; take photographs and make video recordings; take samples of the Defendants' in-process materials, finished products, containers, packaging material, labeling, and other material; and examine and copy all records relating to the receipt, processing, packing, repacking, labeling, holding, and distribution of any and all of the Defendants' products 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.

20. Defendants shall promptly provide any information or records to FDA upon request regarding the receipt, processing, packing, repacking, labeling, holding, and distribution of Defendants' products.

21. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of 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 or fraction thereof per representative for inspection and investigative work; $107.09 per hour or fraction thereof per representative for analytical or review work; $0.575 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-eight (28) days of receiving written notification from FDA of the costs.

NOTICE REQUIREMENTS

22. Within seven (7) 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 on all websites under Defendants' control (including but not limited to arthritisinformation.net, bulkmsm.com, chelationtherapyonline.com, heart-disease-bypass-surgery.com, oralchelation.com, vibrantlifemsm.com, and vibrantlifenews.com). Defendants shall ensure that the Decree remains posted for as long as the Decree remains in effect. Within fourteen (14) 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. If Defendants do not have a facility or website, the affidavit shall so state.

23. Within fourteen (14) days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree. Within twenty (20) 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. If there are no Associated Persons, the affidavit shall so state and no affidavit is required under Paragraph 24.

24. Within fourteen (14) 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-eight (28) 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.

25. 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 certified mail (return receipt requested) to such Associated Person(s). Within seven (7) days of 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 executed certified mail return receipts.

26. Defendants shall notify FDA in writing at least fourteen (14) 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 Clifford Woods LLC, or Vibrant Life, 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-eight (28) days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than fourteen (14) days prior to such assignment or change in ownership.

27. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence" and addressed to the Director, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, United States Food and Drug Administration, 10903 New Hampshire Avenue, White Oak Building 32 Room 4360, Silver Spring, Maryland 20993, and shall reference this civil action by case name and civil action number.

VIOLATIONS OF THIS DECREE

28. If any Defendants fail to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: four thousand dollars ($4,000) in liquidated damages for each day such violation continues; an additional sum of four thousand dollars ($4,000) in liquidated damages per day per violation, for each violation of this Decree, the Act, or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail

value of any product distributed in violation of this Decree, the Act, or its implementing regulations. 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, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

29. 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.

OTHER PROVISIONS

30. 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.

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

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32. 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.

IT IS SO ORDERED,

Date: June 27, 2016

UNITED STATES DISTRICT JUDGE

Entry consented to:
FOR DEFENDANTS

Clifford Woods

CLIFFORD WOODS, Individually and on behalf of CLIFFORD WOODS, LLC d/b/a Vibrant Life

SHARON APPELBAUM
Law Offices of Sharon Appelbaum
401 Wilshire Blvd., 12th Fl., Santa Monica, CA 90401
310-853-0829
Sharon@sharonappelbaumlaw.com

Attorney for CLIFFORD WOODS and CLIFFORD WOODS, LLC d/b/a Vibrant Life

FOR THE UNITED STATES OF AMERICA

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
U.S. Department of Justice
Civil Division

JONATHAN F. OLIN
Deputy Assistant Attorney General

MICHAEL S. BLUME
Director
Consumer Protection Branch

JILL FURMAN
Deputy Director

By: Daniel Zytnick

DANIEL ZYTNICK
Trial Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
202-598-8337
Daniel.E.Zytnick@usdoj.gov

OF COUNSEL:
~~WILLIAM B. SCHULTZ~~ Margaret M. Dotzel
Acting General Counsel
ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division
PERHAM GORJI
Deputy Chief Counsel for Litigation
CLAUDIA J. ZUCKERMAN
Senior Counsel

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 31, Room 4550
Silver Spring, MD 20993-0002
301-796-8609