Exhibit B

FILED IN CHAMBERS

OCT 04 2017

U.S. MAGISTRATE JUDGE
N.D.GEORGIA

DUPLICATE

(USAO GAN 6/10) Search Warrant

United States District Court

NORTHERN DISTRICT OF GEORGIA

ATLANTA DIVISION

In the Matter of the Search of

6015 Unity Drive, Suites A, B, D and F Norcross, GA 30071.

APPLICATION AND AFFIDAVIT FOR SEARCH WARRANT
1:17-MC-1136

I, Gerald Dunham, being duly sworn depose and say:

I am a Special Agent with Food and Drug Administration-Office of Criminal Investigations ("FDA-OCI") and have reason to believe that on the property described as:

See Attachment A-1,

in the Northern District of Georgia there is now concealed certain property, certain information, and certain data, namely,

See Attachment B,

which constitutes evidence of a crime, contraband, fruits of crime, or items illegally possessed, and property designed for use, intended for use, or used in committing a crime, concerning violations of Title 21, United States Code, Sections 331(a), 331(k), 333(a)(1), and 333(a)(2). The facts to support a finding of Probable Cause are as follows:

SEE ATTACHED AFFIDAVIT

Continued on attached sheet made a part hereof.

Signature of Affiant

Gerald Dunham

Sworn to before me, and subscribed in my presence

October 4, 2017 @ 2:35 pm
Date

Atlanta, Georgia
City and States

ALAN J. BAVERMAN
UNITED STATES MAGISTRATE JUDGE
Name and Title of Judicial Officer

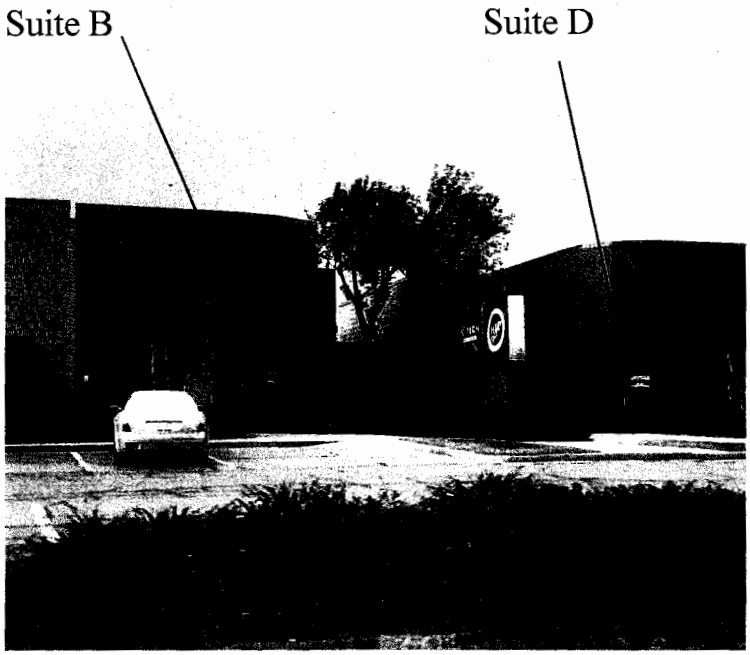
Signature of Judicial Officer

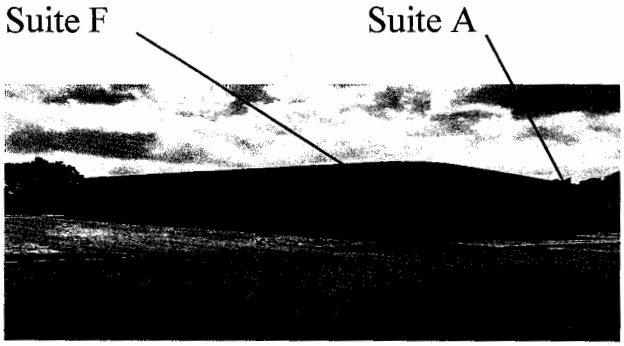
AUSA Steven D. Grimberg

ATTACHMENT A-1

SUBJECT LOCATION 1, a business property located at 6015 Unity Drive, Suites A, B, D and F Norcross, GA 30071. A picture of the location is incorporated herein.

Front View





Suite A is located within the business complex of 6015 Unity Drive. The front door to Suite A is located on the northwest side of the building (on the back side of Suite B) and has glass doors with no descriptive markings. Suite F is located within the business complex of 6015 Unity Drive. The front door to Suite F is located on the northeast side of the building (on the backside of Suite D) and contains a green in color sign on the door marked as 6015-F.

ATTACHMENT B

Evidence, fruits, and instrumentalities of violations of federal law, including Title 21, United States Code, Section 331(a) and (k). This evidence, fruits, and instrumentalities include:

1. Any finished or in-process dietary supplements and/or food containing or labeled as containing DMAA or its chemical equivalent.

2. Raw materials, ingredients, and/or bulk powders containing or labeled as containing DMAA or its chemical equivalent.

3. All labels, labeling, and advertisements pertaining to dietary supplements and/or food containing or labeled as containing DMAA or its chemical equivalent, including magazines, videotapes, handouts, inserts, flyers, and other promotional material.

4. Paraphernalia for manufacturing, packaging, weighing, or distributing dietary supplements and/or food containing or labeled as containing DMAA or its chemical equivalent.

AFFIDAVIT IN SUPPORT OF A SEARCH WARRANT

I, **GERALD DUNHAM**, a Special Agent with the United States Food and Drug Administration's Office of Criminal Investigations ("FDA-OCI"), being first duly sworn, hereby depose and state that:

INTRODUCTION

1. I am the Affiant herein and an investigative or law enforcement officer of the United States empowered to conduct investigations of or to make arrests for offenses under the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Sections 301-399f ("FDCA").

2. I submit this Affidavit in support of an application for a search warrant for the following business locations operated by Hi-Tech Pharmaceuticals, Inc. (referred to collectively as the "SUBJECT LOCATIONS"):

- "SUBJECT LOCATION 1" is a business property located at 6015 Unity Drive, Suites A, B, D and F, Norcross, GA 30071. A description of "SUBJECT LOCATION 1" is detailed in Attachment A-1, which is incorporated herein by reference.
- "SUBJECT LOCATION 2" is a business property located at 6020 Unity Drive, Suites D, E, F, G and H, Norcross, GA 30071. A description of "SUBJECT LOCATION 2" is detailed in Attachment A-2, which is incorporated herein by reference.

- "SUBJECT LOCATION 3" is a business property located at 6025 Unity Drive, Norcross, GA 30071. A description of "SUBJECT LOCATION 3" is detailed in Attachment A-3, which is incorporated herein by reference.
- "SUBJECT LOCATION 4" is a business property located at 5440 Oakbrook Parkway, Suites A and B, Norcross, GA 30093. A description of "SUBJECT LOCATION 4" is detailed in Attachment A-4, which is incorporated herein by reference.
- "SUBJECT LOCATION 5" is a business property located at 500 Satellite Blvd., Suite B, Suwanee, GA 30024. A description of "SUBJECT LOCATION 5" is detailed in Attachment A-5, which is incorporated herein by reference.
- "SUBJECT LOCATION 6" is a business property located at 1256 Oakbrook Drive, Suite A, Norcross, GA 30093. A description of "SUBJECT LOCATION 6" is detailed in Attachment A-6, which is incorporated herein by reference.

3. There is probable cause to believe that Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") is violating the following federal laws in the Northern District of Georgia and elsewhere: (1) Title 21, United States Code, Sections 331(a), and 333(a)(1) and (a)(2) (introducing and delivering for introduction into interstate commerce adulterated foods); and (2) Title 21, United States Code, Section 331(k), and 333(a)(1) and (a)(2) (doing an act to a food after shipment in interstate commerce and while held for sale that results in the food being adulterated). There also is probable cause to believe that the SUBJECT LOCATIONS contain evidence of the aforementioned federal offenses and related offenses, as further described in Attachment B.

4. The facts set forth in this Affidavit are based on: (a) my personal observations; (b) my training and experience; and (c) information obtained from other agents and witnesses. Because I submit this Affidavit for the limited purpose of showing probable cause, I have not included each and every fact that I have learned in this investigation in this Affidavit. Rather, I have set forth only facts sufficient to establish probable cause to issue a Search Warrant for the SUBJECT LOCATIONS. Additionally, unless indicated otherwise, all statements and conversations described herein are related in substance and part only rather than verbatim.

AFFIANT'S BACKGROUND

5. I currently am employed as a Special Agent with the FDA-OCI, Atlanta Resident Office, and have been employed by the FDA-OCI since February 2008. Prior to being employed by the FDA-OCI as a Special Agent, I was employed for eight years as a Special Agent with the United States Department of Health and Human Services, Office of Inspector General, Office of Investigations. I am a graduate of the Federal Law Enforcement Training Center in Brunswick, Georgia.

6. In connection with my official duties, I have received training, both formal and informal, in the enforcement of the FDCA, and have conducted investigations related to the manufacturing and distribution of adulterated foods and drugs. Based upon my training and experience, I am also familiar with the ways in which manufacturers and distributors of adulterated foods conduct their business, including the use of their place of business to create, send, receive and maintain business records associated with their illegal activity.

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

7. FDA is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the FDCA. One purpose of the FDCA is to ensure that foods sold for consumption by humans are safe to eat

and bear labeling containing only true and accurate information. The FDA's responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of foods shipped or received in interstate commerce.

8. The FDCA defines "food" as "articles used for food or drink for man or other animals" or "articles used for components of any such article." 21 U.S.C. § 321(f).

9. Under the FDCA, the term "dietary supplement" means a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (a) a vitamin; (b) a mineral; (c) an herb or other botanical; (d) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (f) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (a), (b), (c), (d), or (e). 21 U.S.C. § 321(ff)(1). Products that meet the statutory definition of "dietary supplements" under the FDCA are deemed to be a "food" within the meaning of the statute. 21 U.S.C. § 321(ff).

10. Under the FDCA, the term "food additive" includes a substance intended to become a component of food, unless such substance has been generally recognized, among experts qualified by scientific training and experience to

evaluate its safety, as having been adequately shown to be safe under the conditions of its intended use. 21 U.S.C. § 321(s).

11. A food additive is deemed to be "unsafe" for the purposes of the FDCA if, among other reasons not applicable here, FDA has not issued a regulation prescribing the conditions under which such food additive can be safely used. 21 U.S.C. § 348(a)(2).

12. Under the FDCA, foods, including dietary supplements, are deemed to be adulterated if they contain an unsafe food additive. 21 U.S.C. § 342(a)(2)(C)(i).

13. The FDCA prohibits doing and causing the following acts:

a. Introducing or delivering for introduction into interstate commerce any food that is adulterated. 21 U.S.C. § 331(a); and

b. Doing an act to a food after shipment in interstate commerce and while held for sale that results in the food being adulterated. 21 U.S.C. § 331(k).

STATEMENT OF PROBABLE CAUSE

14. On September 28, 2017, United States Magistrate Judge Russell G. Vineyard authorized search and seizure warrants at the Subject Locations, all of which are associated with Hi-Tech Pharmaceuticals, Inc. A signed copy of the Application and Affidavit in Support of Search Warrant for Subject Location 1 is attached hereto as Exhibit 1. The affidavit supporting the search and seizure warrants, as

well as Attachment B identifying the items authorized to be seized pursuant to the search warrants, is the same for all the Subject Locations.

15. On October 4, 2017, while executing the search and seizure warrants at the Subject Locations, FDA-OCI Special Agents observed in plain view products labeled to contain DMAA (also known as "1, 3 Dimethylamylamine") or its chemical equivalent, as well as bulk containers of raw product labeled as containing DMAA or its chemical equivalent (the "Current DMAA Products"). Current DMAA Products were observed in either raw form and/or finished products at all six of the Subject Locations.

16. The search warrants authorize the seizure of, among other things, "[a]ny misbranded and/or adulterated foods and/or drugs, including but not limited to products purportedly labeled as dietary supplements." *See* Exhibits 1, Attachment B, Item (1). The Current DMAA Products are considered to be adulterated under the FDCA.

17. On or about November 7, 2013, the United States commenced a civil seizure action in the Northern District of Georgia, seeking forfeiture and condemnation of unidentified quantities of finished and/or in-process food products, raw materials, and/or bulk ingredients containing DMAA located at Hi-Tech's 5440 Oakbrook Parkway, Norcross, Georgia facility (i.e., SUBJECT LOCATION 4). *See United*

States v. Quantities of Finished and In-Process Foods, et al., 1:13-CV-3675-WBH (N.D. Ga.) ("the Civil Seizure Action").

18. On or about April 3, 2017, the Court entered judgment in the Government's favor in the Civil Seizure Action, concluding that Hi-Tech's products containing DMAA were adulterated foods, and thus, ordered that the seized articles be condemned and forfeited to the United States. *See id.* at Doc. No. 140 (N.D. Ga. April 3, 2017). A copy of the Court's order is attached hereto as Exhibit 2. Hi-Tech thereafter filed a motion to reconsider, which the Court denied. *See id.* at Doc. No. 148 (N.D. Ga. June 2, 2017). Hi-Tech thereafter filed a Notice of Appeal to the Eleventh Circuit, which is pending. *See id.* at Doc. No. 149 (N.D. Ga. July 26, 2017).

19. The Court's reasoning in the Civil Seizure Action, *i.e.,* that DMAA is an unsafe food additive, thus rendering food containing DMAA adulterated, also applies to the Current DMAA Products observed by FDA-OCI at the SUBJECT LOCATIONS.

20. Although the search warrants executed at the Subject Locations authorize law enforcement to seize adulterated foods, and the Current DMAA Products constitute adulterated foods, I am seeking this supplemental search warrant to authorize the seizure of the Current DMAA Products in an abundance of caution.

CONCLUSION

21. For the foregoing reasons, there is probable cause to believe that, by continuing to purchase and receive DMAA as a raw ingredient, and then manufacturing, marketing, and distributing DMAA-containing food (*i.e.*, dietary supplements), Hi-Tech is violating the following federal laws: (1) Title 21, United States Code, Sections 331(a), and 333(a)(1) and (a)(2) (introducing and delivering for introduction into interstate commerce adulterated foods); and (2) Title 21, United States Code, Section 331(k), and 333(a)(1) and (a)(2) (doing an act to a food after shipment in interstate commerce and while held for sale that results in the food being adulterated). Furthermore, I have probable cause to believe that evidence of the type described in Attachment B to this Affidavit, which constitutes evidence of the aforementioned federal violations, is currently located at the SUBJECT LOCATIONS.

Exhibit 1

DUPLICATE

FILED IN CHAMBERS
U.S.D.C. - Atlanta
SEP 28 2017
James N. Hatten, Clerk
By: Deputy Clerk

(USAO GAN 6/10) Search Warrant

United States District Court

NORTHERN DISTRICT OF GEORGIA

ATLANTA DIVISION

In the Matter of the Search of

6015 Unity Drive, Suites A, B, D and F Norcross, GA 30071.

APPLICATION AND AFFIDAVIT FOR SEARCH WARRANT
1:17-MC-1106
UNDER SEAL

I, Brian Kriplean, being duly sworn depose and say:

I am a Special Agent with Food and Drug Administration-Office of Criminal Investigations ("FDA-OCI") and have reason to believe that on the property described as:

See Attachment A-1,

in the Northern District of Georgia there is now concealed certain property, certain information, and certain data, namely,

See Attachment B,

which constitutes evidence of a crime, contraband, fruits of crime, or items illegally possessed, and property designed for use, intended for use, or used in committing a crime, concerning violations of Title 21, United States Code, Section(s) 331(a), 333(a)(2), 331(k), 841(a)(1). The facts to support a finding of Probable Cause are as follows:

SEE ATTACHED AFFIDAVIT

Continued on attached sheet made a part hereof.

Sworn to before me, and subscribed in my presence

Signature of Affiant

Brian Kriplean

September 28, 2017
Date

Atlanta, Georgia
City and States

RUSSELL G. VINEYARD
UNITED STATES MAGISTRATE JUDGE
Name and Title of Judicial Officer

Signature of Judicial Officer

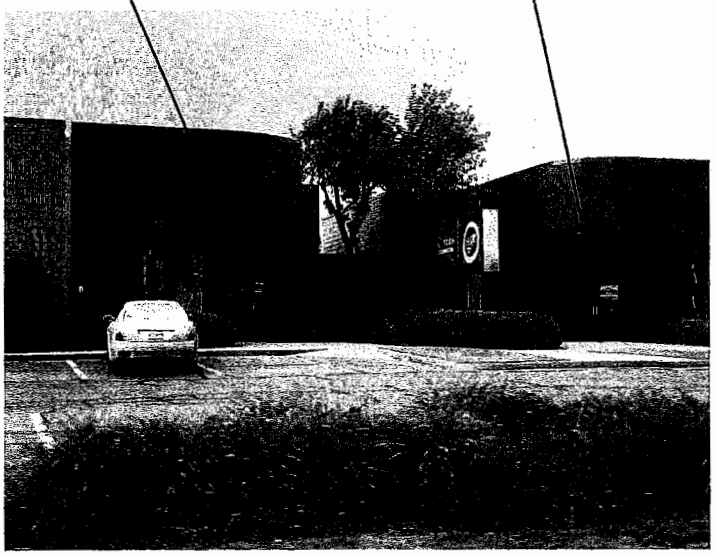
AUSA Steven D. Grimberg, 6367

ATTACHMENT A-1

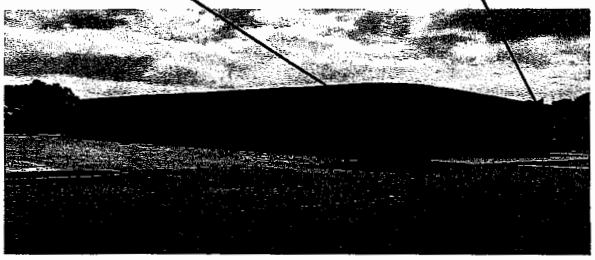
SUBJECT LOCATION 1, a business property located at 6015 Unity Drive, Suites A, B, D and F Norcross, GA 30071. A picture of the location is incorporated herein.

Front View

Suite B Suite D



Suite F Suite A



Suite A is located within the business complex of 6015 Unity Drive. The front door to Suite A is located on the northwest side of the building (on the back side of Suite B) and has glass doors with no descriptive markings. Suite F is located within the business complex of 6015 Unity Drive. The front door to Suite F is located on the northeast side of the building (on the backside of Suite D) and contains a green in color sign on the door marked as 6015-F.

ATTACHMENT B

Evidence, fruits, and instrumentalities of violations of federal law, including 21 U.S.C. § 331 and 21 U.S.C. § 841(a)(1). This evidence, fruits, and instrumentalities include:

1. Any misbranded and/or adulterated foods and/or drugs, including but not limited to products purportedly labeled as dietary supplements.

2. Any Schedule III controlled substances in whatever form present.

3. Raw materials and bulk powders used to distribute controlled substances and/or manufacture misbranded and/or adulterated foods and/or drugs.

4. All labels, labeling, and advertisements pertaining to misbranded and/or adulterated foods and/or drugs, including magazines, videotapes, handouts, inserts, flyers, and other promotional material.

5. Paraphernalia for manufacturing, packaging, weighing, or distributing controlled substances or misbranded and/or adulterated foods and/or drugs.

6. All electronic devices, including but not limited to, computers, routers, modems, hard drives, flash drives, cell phones, printers and label making

devices utilized in any capacity involving the manufacturing or distribution of controlled substances and/or adulterated foods and/or drugs.

7. All business records and related correspondence, in whatever form, including handwritten and computer-generated, pertaining to the illegal purchase, possession, and/or unauthorized distribution of controlled substances and introduction into interstate commerce any misbranded and/or adulterated foods and/or drugs. The documents to be seized include those relating to the brokering, ordering, producing, purchasing, shipping, selling and distributing of misbranded and/or adulterated foods and/or drugs, including but not limited to: business journals and ledgers; purchase orders; invoices; contracts; receipts; delivery receipts; work orders; production records, batch records, recipes, product formulations, laboratory test results, certificates of content, certificates of analysis, certificates of free sale, GMP certifications, GMP audit reports, telephone, telefax, and computer Internet records; written and electronic correspondence; bank records, including bank statements; records of investment accounts; financial statements and summaries; letters of credit; canceled checks, check registers, and other records reflecting payments; airway bills; bills of lading; handwritten notes; memoranda; address books; sales orders; purchase orders; rolodexes, business cards, and other documents identifying suppliers and customers; shippers' letters of instructions; business inquiries;

confirmations; commodity business brochures; supplier and customer lists; records of purchase from suppliers; application forms, documents, and literature regarding the FDA and/or State agency; and any unopened mail addressed to or from the individuals/businesses mentioned herein.

8. All tax records, including summaries and schedules.

9. All records relating to property, both real and personal, that may have been acquired with the proceeds of the illegal purchase, possession, and unauthorized distribution of controlled substances or introduction into interstate commerce of any misbranded and/or adulterated foods and/or drugs.

10. Indicia of occupancy, residency, and/or ownership of the premises to be searched.

11. Relating to computer-generated records, such records include:

    A. Any and all information and/or data stored in the form of magnetic or electronic coding on computer media or on media capable of being read by a computer or with the aid of computer-related equipment. This media includes floppy diskettes, fixed hard disks, removable hard disk cartridges, tapes, laser discs, video cassettes and other media that is capable of storing

magnetic coding, as well as punch cards, and/or paper tapes, and all printouts of stored data.

B. Any and all electronic devices that are capable of analyzing, creating, displaying, converting or transmitting electronic or magnetic computer impulses or data. These devices include computers, computer components, computer peripherals, word-processing equipment, modems, monitors, cables, printers, plotters, encryption circuit boards, optical scanners, external hard drives, external tape backup drives and other computer-related electronic devices.

C. Any and all instructions or programs stored in the form of electronic or magnetic media that are capable of being interpreted by a computer or related components. The items to be seized include operating systems, application software, utility programs, compilers, interpreters and other programs or software used to communicate with computer hardware or peripherals either directly or indirectly via telephone lines, radio or other means of transmission.

D. Any and all written or printed material that provides instruction or examples concerning the operation of computer systems or software, and/or any related device, and sign-on passwords, encryption codes or other information needed to access the computer system and/or software programs.

The terms "items," "records" and "documents" include all of the foregoing items of evidence in whatever form and by whatever means such items, records, or documents, their drafts, or their modifications may have been created or stored, including (but not limited to) any handmade form (such as writing, drawing, painting, with any implement on any surface, directly or indirectly); any photographic form (such as microfilm, microfiche, prints, slides, negatives, videotapes, motion pictures, photocopies); any mechanical form (such as phonographic records, printing, or typing); and electronic or magnetic form (such as tape recordings, cassettes, compact discs, or any information on an electronic or magnetic storage device, such as floppy diskettes, hard disks, backup tapes, optical discs, printer buffers, smart cards, memory calculators, electronic dialers, or electronic notebooks, as well as printouts or readouts from any magnetic storage device).

In order to search for data that is capable of being read or interpreted by a computer, law enforcement personnel may need to seize and search the following items:

a. Any computer equipment and storage device capable of being used to commit, further or store evidence of crimes, including but not limited to the introduction into interstate commerce of misbranded and/or

adulterated foods and/or drugs in violation to Title 21 USC § 331, and manufacturing and distributing controlled substances in violation of 21 USC § 841(a)(1).

b. Any computer equipment used to facilitate the transmission, creation, display, encoding or storage of data, including word processing equipment, modems, docking stations, monitors, printers, plotters, encryption devices, and optical scanners;

c. Any magnetic, electronic or optical storage device capable of storing data, such as floppy disks, hard disks, tapes, CD-ROMs, CD-R, CD-RWs, DVDs, optical disks, printer or memory buffers, smart cards, PC cards, memory calculators, electronic dialers, electronic notebooks, and personal digital assistants;

d. Any documentation, operating logs and reference manuals regarding the operation of the computer equipment, storage devices or software;

e. Any applications, utility programs, compilers, interpreters, and other software used to facilitate direct or indirect communication with the computer hardware, storage devices or data to be searched;

f. Any physical keys, encryption devices, dongles and similar physical items that are necessary to gain access to the computer equipment, storage devices

or data; and

g. Any passwords, password files, test keys, encryption codes or other information necessary to access the computer equipment, storage devices or data.

In addition, agents conducting this search are authorized to utilize the service(s) of outside computer expert(s), who may not be Federal Law Enforcement Officer(s), in order to use and operate the computer system(s) at the above specified location(s), for purposes of retrieving the above specified computer information during the course of the authorized search, provided that such expert(s) operate under the direction, supervision, and control of Special Agent(s) of the United States Food and Drug Administration Office of Criminal Investigations.

As used above, the terms "records" and "information" includes all forms of creation or storage, including any form of computer or electronic storage (such as hard disks or other media that can store data); any handmade form (such as writing); any mechanical form (such as printing or typing); and any photographic form (such as microfilm, microfiche, prints, slides, negatives, videotapes, motion pictures, or photocopies).

The term "computer" includes all types of electronic, magnetic, optical, electrochemical, or other high speed data processing devices performing logical, arithmetic, or storage functions, including desktop computers, notebook computers, mobile phones, tablets, server computers, and network hardware.

The term "storage medium" includes any physical object upon which computer data can be recorded. Examples include hard disks, RAM, floppy disks, flash memory, CD-ROMs, and other magnetic or optical media.

AFFIDAVIT IN SUPPORT OF A SEARCH WARRANT

I, Brian C. Kriplean, a Special Agent with the United States Food and Drug Administration Office of Criminal Investigations ("FDA-OCI"), being first duly sworn, hereby depose and state that:

I. INTRODUCTION

1. I am the Affiant herein and an investigative or law enforcement officer of the United States empowered to conduct investigations of or to make arrests for offenses under the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Sections 301-399f ("FDCA").

2. I submit this Affidavit in support of an application for a search warrant for the following business locations operated by Hi-Tech Pharmaceuticals, Inc. (referred to collectively as the "SUBJECT LOCATIONS"):

- "SUBJECT LOCATION 1" is a business property located at 6015 Unity Drive, Suites A, B, D and F, Norcross, GA 30071. A description of "SUBJECT LOCATION 1" is detailed in Attachment A-1, which is incorporated herein by reference.
- "SUBJECT LOCATION 2" is a business property located at 6020 Unity Drive, Suites D, E, F, G and H, Norcross, GA 30071. A description of "SUBJECT LOCATION 2" is detailed in Attachment A-2, which is incorporated herein by reference.

- "SUBJECT LOCATION 3" is a business property located at 6025 Unity Drive, Suite A, Norcross, GA 30071. A description of "SUBJECT LOCATION 3" is detailed in Attachment A-3, which is incorporated herein by reference.
- "SUBJECT LOCATION 4" is a business property located at 5440 Oakbrook Parkway, Suites A and B, Norcross, GA 30093. A description of "SUBJECT LOCATION 4" is detailed in Attachment A-4, which is incorporated herein by reference.
- "SUBJECT LOCATION 5" is a business property located at 500 Satellite Blvd., Suite B, Suwanee, GA 30024. A description of "SUBJECT LOCATION 5" is detailed in Attachment A-5, which is incorporated herein by reference.
- "SUBJECT LOCATION 6" is a business property located at 1256 Oakbrook Drive, Suite A, Norcross, GA 30093. A description of "SUBJECT LOCATION 6" is detailed in Attachment A-6, which is incorporated herein by reference.

3. There is probable cause to believe that Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") is manufacturing, marketing, and distributing misbranded foods and/or drugs, some of which contain Schedule III controlled substances, namely, anabolic steroids. Accordingly, there is probable cause to believe that Hi-Tech is violating federal law in the Northern District of Georgia and elsewhere, including violations of the following statutes: (a) Title 21, United States Code, Sections 331(a) and 333(a)(2) (introducing or delivering for introduction into interstate commerce misbranded foods and/or drugs); (b) Title 21, United States Code, Sections 331(k) and 333(a)(2) (doing an act to a food and/or drug after shipment in interstate commerce and while held for sale that results in the food and/or drug being misbranded); and (c) Title 21, United States Code, Section 841(a)(1) (manufacturing and distributing controlled substances). More specifically, Hi-Tech uses the SUBJECT LOCATIONS as its principal places of business to manufacture and/or distribute misbranded foods and/or drugs, which Hi-Tech markets as "prohormones." There also is probable cause to believe that the SUBJECT LOCATIONS contain evidence of the aforementioned federal offenses and related offenses, as further described in Attachment B, and that evidence is relevant and material to the ongoing investigation being conducted by the FDA-OCI and Internal Revenue Service Criminal Investigations ("IRS-CI").

4. The facts set forth in this Affidavit are based on: (a) my personal observations; (b) my training and experience; and (c) information obtained from other agents/officers and witnesses. Because I submit this Affidavit for the limited purpose of showing probable cause, I have not included each and every fact that I have learned in this investigation in this Affidavit. Rather, I have set forth only facts sufficient to establish probable cause to issue Search Warrants for the SUBJECT LOCATIONS. Additionally, unless indicated otherwise, all statements and conversations described herein are related in substance and part only rather than verbatim.

II. AFFIANT'S BACKGROUND

5. I currently am employed as a Special Agent ("SA") with the FDA-OCI, Nashville Domicile Office, and have been employed by the FDA-OCI since September 2007. Prior to being employed by the FDA-OCI as a Special Agent, I was employed as a Special Agent with IRS-CI. I am a graduate of the Federal Law Enforcement Training Center in Glynco, Georgia. At this training center, I underwent a six-month training program that addressed investigation techniques and other matters.

6. In connection with my official duties, I investigate criminal violations of the FDCA and related offenses. I have received training, both formal and informal, in the enforcement of the FDCA, investigation of the manufacture and distribution of

misbranded foods and/or drugs, undercover operations, interviewing techniques, and the use of physical and electronic surveillance.

7. I am familiar with and have used many of the traditional methods of investigation, including, without limitation, visual surveillance, electronic surveillance, informant and witness interviews, consensually recorded telephone conversations, defendant debriefings, the use of confidential sources, undercover operations, execution of search warrants, the seizure of evidence, and controlled purchases of misbranded foods and/or drugs.

8. Based upon my training and experience, I am familiar with the ways in which manufacturers and distributors of misbranded foods and/or drugs conduct their business, including the use of their place of business to create, send, receive and maintain business records associated with their illegal activity.

III. APPLICABLE STATUTES

The Federal Food, Drug, and Cosmetic Act

9. FDA is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the FDCA. One purpose of the FDCA is to ensure that foods sold for consumption by humans are safe to eat and bear labeling containing only true and accurate information. FDA also ensures that drugs are safe and effective for their intended uses and bear labeling that

contains true and accurate information. The FDA's responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of foods and drugs shipped or received in interstate commerce.

10. Under the FDCA, foods and drugs are deemed to be misbranded if their respective labeling is false or misleading in any particular. 21 U.S.C. §§ 343(a)(1) (foods) and 352(a) (drugs). A drug is also misbranded if its labeling fails to bear adequate directions for use. 21 U.S.C. § 352(f)(1).

11. The FDCA prohibits doing and causing the following acts:

a. Introducing or delivering for introduction into interstate commerce any food and/or drug that is misbranded. 21 U.S.C. § 331(a); and

b. Doing an act to a food and/or drug after shipment in interstate commerce and while held for sale that results in the food and/or drug being misbranded. 21 U.S.C. § 331(k).

The Controlled Substances Act

12. The Controlled Substances Act ("CSA") contains a general definition of anabolic steroids, 21 U.S.C. § 802(41)(A), a list of specific substances that meet the definition of anabolic steroid, 21 U.S.C. § 802(41)(A)(i) – (lxxv), and a complementary definition, 21 U.S.C. § 802(41)(C), that covers other substances that may be considered anabolic steroids under the CSA.

13. Anabolic steroids are Schedule III Controlled Substances. 21 U.S.C. § 812(b), Schedule III(e). With certain exceptions authorized by law, it is unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute or dispense, a controlled substance. 21 U.S.C. § 841(a)(1).

IV. PROBABLE CAUSE

14. According to records filed with the State of Georgia Secretary of State Corporations Division, Hi-Tech was incorporated by Jared Wheat on April 6, 1998. According to the annual filings of Hi-Tech filed with the State of Georgia since October 2007 through January 2017, SUBJECT LOCATION 1 is listed as the principal office address of record.

15. Hi-Tech has an active food facility registration with the FDA, which was last updated by Hi-Tech on November 7, 2016. That registration is valid through December 31, 2018. The registration lists SUBJECT LOCATION 1 as the food facility address.

16. According to FDA records, Hi-Tech has multiple Facility FDA Establishment Identifier ("FEI) Numbers assigned to it. Facility FEIs are assigned by the FDA to track inspections. SUBJECT LOCATIONS 1, 4, 5 and 6 have Facility FEIs assigned.

17. According to FDA records, Hi-Tech's registered facilities in Georgia were last inspected by the FDA in October 2013. The inspected facilities included SUBJECT LOCATIONS 1, 2, 4 and 5. At the time of that inspection, SUBJECT LOCATION 1 (consisting of Suites B and D) served as Hi-Tech's administrative offices and manufacturing facility, respectively. SUBJECT LOCATION 2 (consisting of Suites F and G) served as an additional manufacturing facility. SUBJECT LOCATION 4 served as a warehouse for raw material storage, finished products, bulk dietary supplements, packaging material, and manufacturing machinery. SUBJECT LOCATION 5 served as a facility for blending powder products and raw materials. During the course of the inspection, FDA regulators observed manufacturing activities and reviewed and collected various business records pertaining to Hi-Tech's manufacture and distribution of purported dietary supplements. Such records included batch records, importation of raw material documents, operating procedures, and shipping records.

18. Beginning in or around August 2011, I have been involved in several investigations involving products manufactured and distributed by Hi-Tech. Through such investigations, I have become familiar with the physical locations (SUBJECT LOCATIONS) and websites operated by Hi-Tech, including www.hitechpharma.com. Such website is utilized to promote Hi-Tech's business operations and products it manufactures and distributes. Such website also serves

as an online retail store in which a consumer can order purported dietary supplement products manufactured by Hi-Tech.

19. I have conducted a search of the www.hitechpharma.com domain name through a public domain registration database. The registrant of the hitechpharma.com domain name was listed as "Hi-Tech Pharmaceuticals, Inc." located at SUBJECT LOCATION 1.

20. In August 2017, I visited the website of www.hitechpharma.com. During the review of the website, I observed numerous Hi-Tech branded products being marketed for sale under the category of "Testosterone & Prohormone Supplements," including 1-AD, 1-Testosterone, Androdiol, Equibolin, and Superdrol. Through training and experience, I am aware that "prohormone" supplements are marketed to promote muscle growth. I am further aware from other similar investigations that prohormone supplements often contain non-dietary ingredients or Schedule III controlled substances, namely anabolic steroids.

21. Previously, in September 2016, agents from FDA-OCI conducted undercover purchases of the aforementioned products from www.hitechpharma.com using undercover names and credit cards. Those products were subsequently received via UPS Ground delivery to FDA-OCI undercover addresses in Florida and Georgia. Each shipment listed the shipper as being

located at SUBJECT LOCATION 6. Each shipment contained a printed invoice from Hi-Tech listing its address as SUBJECT LOCATION 1.

22. Following receipt of the undercover purchases, the products were submitted to FDA's Forensic Chemistry Center (FCC) for chemical analysis. The FDA-FCC reported that the following Hi-Tech products contained Schedule III anabolic steroids:

Product	**Schedule III Anabolic Steroids**	**Alternate Name of Steroids**
1-AD Lot # C736	boldione; and androstanedione	androstadienedione and/or 1,4-androstadien-3,17-dione 5α-androstan-3,17-dione
1-Testosterone Lot # C737	boldione; and androstanedione	androstadienedione and/or 1,4-androstadien-3,17-dione 5α-androstan-3,17-dione
Androdiol Lot # C750	4-androstenediol and/or 5-androstenediol	4-androsten-3β, 17β-diol 5-androsten-3β-ol-17-one
Equibolin Lot # C689	4-androstenediol and/or 5-androstenediol	4-androsten-3β, 17β-diol 5-androsten-3β-ol-17-one
Superdrol Lot # C770	androstanedione	5α-androstan-3,17-dione

23. The respective labeling for the 1-AD, 1-Testosterone, Androdiol, Equibolin, and Superdrol products received from the September 2016 undercover purchases failed to properly declare as ingredients the respective Schedule III anabolic steroids contained therein, as more fully detailed in the table above. Accordingly,

this false or misleading labeling rendered those products misbranded under the FDCA. *See* 21 U.S.C. § 343(a)(1) (foods) and 352(a) (drugs).

24. On August 7, 2017, a cooperating source (CS)[1] sent an email to Chad Jordan, Regional Sales Manager for Hi-Tech, requesting information on Hi-Tech's prohormones. In response, Jordan sent an email to the CS on August 8, 2017 from chadj@hitechpharma.com stating in part that "all are compliant and DHEA compounds that bypass the liver so they are not toxic. 34.95 is your price on all of the prohormones under the hi tech line. 1-testosterone is the one I move the most and then Anavar is my second best seller." Additionally, Jordan provided the CS with a dropbox link containing price sheets for Hi-Tech's products and its family of brands. The link also contained marketing material and labels for numerous

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1 The CS is considered an un-indicted co-conspirator in an unrelated investigation and pending criminal case in the Northern District of Georgia. The CS owned and operated a nutrition retail store and distributed a privately labeled brand of dietary supplements that he sold to end-user consumers. The investigation determined that the CS distributed products containing controlled substances, specifically anabolic steroids, which were manufactured by co-conspirators who have been indicted. The products containing controlled substances that were distributed by the CS were misbranded in that they did not disclose on the labeling that the products contained anabolic steroids. The CS agreed to voluntarily cooperate with law enforcement and has not been charged to date.

products Hi-Tech distributes. On August 14, 2017, the CS emailed Jordan to inquire about payment options. In response, Jordan replied in part "really just have two options. We can do COD if you fill out the COD form. Or we can take a credit card for the order." On August 15, 2017, the CS emailed Jordan to place an order for five bottles each of the products listed in paragraph 22 above via COD payment.

25. On August 21, 2017, a UPS COD shipment was delivered to the CS in North Carolina from Hi-Tech. The shipment listed the shipper as located at SUBJECT LOCATION 6. I took custody of the parcel, which was sealed when I received it, and subsequently inventoried its contents. The shipment contained a printed invoice dated August 17, 2017, from Hi-Tech listing its address as SUBJECT LOCATION 1. The shipment also contained five sealed bottles each of 1-AD, Androdiol, Equibolin, and Superdrol bearing the same label information but with different lot numbers from the lot numbers listed on the previously purchased products received in September 2016. I am aware that such products are commonly manufactured in batches with a unique lot number assigned to each batch.

26. One bottle of each of the four products received from the undercover purchase in August 2017 was subsequently submitted to FDA-FCC for chemical analysis. FDA-FCC reported the following products contained Schedule III

anabolic steroids, as more fully detailed below:

Product	**Schedule III Anabolic Steroids**	**Alternate Name of Steroids**
1-AD Lot # C921	4-androstenediol and/or 5-androstenediol	4-androsten-3β, 17β-diol 5-androsten-3β-ol-17-one
Androdiol Lot #C681	4-androstenediol and/or 5-androstenediol	4-androsten-3β, 17β-diol 5-androsten-3β-ol-17-one
Equibolin Lot # C841	4-androstenediol and/or 5-androstenediol	4-androsten-3β, 17β-diol 5-androsten-3β-ol-17-one
Superdrol Lot # C857	androstanedione; 4-androstenediol and/or 5-androstenediol; and boldione	5α-androstan-3,17-dione 4-androsten-3β, 17β-diol 5-androsten-3β-ol-17-one androstadienedione and/or 1,4-androstadien-3,17-dione

27. The respective labeling for the 1-AD, Androdiol, Equibolin, and Superdrol products received from the August 2017 undercover purchase failed to properly declare as ingredients the respective Schedule III anabolic steroids contained therein, as more fully detailed in the table above. Accordingly, this false or misleading labeling rendered those products misbranded under the FDCA. *See* 21 U.S.C. § 343(a)(1) (foods) and 352(a) (drugs).

28. On September 14, 2017, I visited the website www.hitechpharma.com. The Hi-Tech website continued to offer for sale the products listed in paragraphs 22 and 26 above.

29. In August 2017, I received and reviewed lease agreements and other landlord records obtained from Plaza 85 SPE, LLC, the owner of Plaza 85 Business Park where SUBJECT LOCATIONS 1, 2 and 3 are located. Such records reflect that Hi-Tech entered into an industrial lease agreement for all three premises beginning on June 10, 2014. A June 2016 addendum to the lease agreement for SUBJECT LOCATIONS 1, 2 and 3 shows a lease expiration of May 30, 2020. Additional landlord records reflect the rent payments on the above-described premises being paid from funds derived from a Bank of America checking account in the name of "Diversified Biotech Inc dba Hi-Tech Pharmaceuticals" located at SUBJECT LOCATION 2.

30. In August 2017, I received and reviewed lease agreements and other landlord records obtained from MDH Partners, LLC, owner and landlord of SUBJECT LOCATION 4. Such records reflect that Hi-Tech entered into a lease agreement with the landlord effective November 10, 2011, for the premises at SUBJECT LOCATION 4 consisting of approximately 42,106 rentable square feet. On January 10, 2013, Hi-Tech executed an amendment to this lease agreement by

expanding the leased premises to include Suite B consisting of approximately 14,106 additional rentable square feet. This lease agreement is valid through April 30, 2018. Additional records reflect the rent payments on the above described premises being paid from funds derived from a Bank of America checking account in the name of "Diversified Biotech Inc dba Hi-Tech Pharmaceuticals" located at SUBJECT LOCATION 2.

31. In May 2017, I received and reviewed lease agreements and other landlord records obtained from Stream Realty Partners, third party property management service provider for SUBJECT LOCATION 6. Such records reflect that Hi-Tech entered into an industrial lease agreement with the landlord effective October 29, 2015, for the premises at SUBJECT LOCATION 6. On February 16, 2016, Hi-Tech executed an amendment to this lease agreement by expanding the leased premises to include Suite B-1 consisting of approximately 5,036 additional rentable square feet. This lease is valid through November 30, 2020. Additional records reflect the rent payments on the above described premises being paid from funds derived from a Bank of America checking account in the name of "Diversified Biotech Inc dba Hi-Tech Pharmaceuticals" located at SUBJECT LOCATION 2.

32. According to records obtained from UPS in June 2017, Shipping Account #X2062W is listed in the name of "Hi-Tech Pharmaceutical" at the address of SUBJECT LOCATION 4. This account started in September 1997 and remains active with UPS. Records reflect in excess of 3,700 packages were picked up by UPS between January 2015 and May 15, 2017, listing Hi-Tech Pharmaceutical at SUBJECT LOCATION 4 as the consignee.

33. According to records obtained from UPS in June 2017, Shipping Account #2F5Y87 is listed in the name of "Hitech Pharma Small Package" at the address of SUBJECT LOCATION 6. This account started in December 2015 and remains active with UPS. Records reflect in excess of 57,000 shipments were billed to this account by UPS between February 2016 and May 15, 2017. Such shipments include the three undercover purchases made in September 2016.

34. On August 22, 2017, I received information from UPS regarding COD remittances for UPS Account #2F5Y87. Specifically, UPS stated that COD remittances for this account are sent via US mail to Hi-Tech Pharmaceutical at SUBJECT LOCATION 1.

35. On August 24, 2017, Task Force Officers assigned to FDA-OCI conducted surveillance activities in the late evening hours at various SUBJECT LOCATIONS. At approximately 11:30pm, officers observed several vehicles parked in the parking lot between SUBJECT LOCATIONS 1 and 3. I am aware

from information obtained throughout this investigation that Hi-Tech operates its manufacturing and production facilities over multiple shifts when necessary to meet demand. Officers subsequently traveled to SUBJECT LOCATION 5 where officers observed two box trucks parked in the rear of the building along with several shipping bags commonly used to ship dry bulk materials laying on a railing near loading docks.

36. On August 29, 2017, Task Force Officers assigned to FDA-OCI conducted surveillance activities in the early afternoon hours at various SUBJECT LOCATIONS. Officers observed a male person exit SUBJECT LOCATION 2 and enter SUBJECT LOCATION 1. Officers observed a white box truck bearing GA tag DWL301 depart SUBJECT LOCATION 2 and park in front of SUBJECT LOCATION 1. The male driver was observed entering SUBJECT LOCATION 1 for a few minutes before departing in the truck. Officers continued mobile surveillance of the box truck where it was observed arriving at the rear of SUBJECT LOCATION 5 where loading docks are known to exist. According to vehicle registration databases, this vehicle is registered to Hi-Tech at SUBJECT LOCATION 1. Officers subsequently traveled to SUBJECT LOCATION 4 where a black GMC Yukon bearing GA tag PXI2329 was observed parked in front of SUBJECT LOCATION 4. According to vehicle registration databases, this

vehicle is registered to Olen Harris whom is known by me to be employed at Hi-Tech in sales. This vehicle was previously observed parked at SUBJECT LOCATION 1. Officers observed several loading docks with doors open in the rear of SUBJECT LOCATION 4. By way of looking through the open loading dock doors, officers were able to observe extensive shelving throughout the interior of the warehouse which contained large amounts of shipping style boxes.

37. On September 7, 2017, Task Force Officers assigned to FDA-OCI conducted surveillance activities in the early afternoon hours at various SUBJECT LOCATIONS. Officers observed the same black GMC Yukon bearing GA tag PXI2329 parked in front of SUBJECT LOCATION 1. Officers further observed a white box truck marked with business lettering which read "Hi-Tech Pharmaceuticals" parked at a loading dock of SUBJECT LOCATION 2. Officers also observed a yellow box truck bearing WI tag DG84387 parked at SUBJECT LOCATION 1. Officers subsequently traveled to SUBJECT LOCATION 4 where they observed loading docks in the rear of the building with open doors. Officers were able to observe through the open loading dock doors numerous shelves containing large amounts of shipping boxes square in shape. Officers also observed numerous shelves storing cardboard drums consistent with drums used to ship bulk powders. Officers also observed a trash dumpster near the loading docks which appeared to be at full capacity. Officers subsequently traveled to SUBJECT

LOCATION 6 where a UPS tractor trailer was backed into a loading dock located in the rear of SUBJECT LOCATION 6.

38. On September 20, 2017, I conducted surveillance activities in the early evening hours at various SUBJECT LOCATIONS. I observed the loading dock doors in the rear of SUBJECT LOCATION 6 closed and a UPS tractor trailer backed into one of the loading dock doors. Additionally, cardboard boxes were observed lying on the ground next to the trash dumpster. I observed the front entrance of SUBJECT LOCATION 6-Suite B which had a rack containing numerous cardboard boxes blocking the interior entryway. I then traveled to SUBJECT LOCATION 4 where observations were made of the front entrance doors to Suites A, B and C. Suite A appeared to contain space divided by walls. Suites B and C had racks stacked of boxes blocking the interior entryway. Some of the boxes contained shipping labels addressed to "HI-TECH 5440 Oakbrook Parkway Suite A Norcross, GA" listing a P.O. number. Such boxes were from Alpha Packaging which I am aware sells plastic bottles and jars utilized in the manufacturing of supplements. I then traveled to the business complex where SUBJECT LOCATIONS 1, 2 and 3 are located. I observed three white box trucks, one of which contained lettering for Hi-Tech Pharmaceuticals, Inc. parked at or

near the loading docks of SUBJECT LOCATION 2. I further observed workers present at SUBJECT LOCATION 1, Suite F.

39. On September 21, 2017, I continued surveillance activities at various SUBJECT LOCATIONS in the early morning hours. Upon arriving at SUBJECT LOCATION 2, I observed the front entrance doors of Suites G and H containing signs for Hi-Tech Pharmaceuticals. Both suites were illuminated and equipment was present consistent with equipment utilized in the manufacture of supplements. I proceeded to surveil SUBJECT LOCATIONS 1, 2 and 3 where numerous persons were observed wearing clothing and protective/sanitary equipment consistent with the manufacture of supplements. On multiple occasions, such persons were observed coming and going from the three locations. I also observed several box trucks, including those previously described, transiting to and from SUBJECT LOCATIONS 1, 2 and 3.

40. On September 24, 2017, Task Force Officers assigned to FDA-OCI conducted surveillance activities in the early afternoon hours at SUBJECT LOCATIONS 1, 2 and 3. Officers did not observe any work activity being conducted nor any persons present at the locations. Officers were able to observe the interior of SUBJECT LOCATION 3 by looking through the exterior glass doors. Officers observed mixers, scales and bottles atop counters consistent with items utilized in the manufacture of dietary supplements. Officers were able to

photograph the exterior entrances of SUBJECT LOCATIONS 1, 2 and 3. SUBJECT LOCATION 1, Suites B and D; SUBJECT LOCATION 2, Suites D, G and H; and SUBJECT LOCATION 3, Suite A, all have a sign on the door labeled as Hi-Tech Pharmaceuticals. SUBJECT LOCATION 2, Suite F has signage on the door labeled as Hi-Tech Fitness Center.

V. COMPUTER SEARCHES

41. As described above and in Attachment B, this application seeks permission to search for records that might be found on the SUBJECT LOCATIONS, in whatever form they are found. One form in which the records might be found is data stored on a computer's hard drive or other storage media. Thus, the warrant applied for would authorize the seizure of electronic storage media or, potentially, the copying of electronically stored information, all under Rule 41(e)(2)(B).

42. *Probable cause.* I submit that if a computer or storage medium is found on the SUBJECT LOCATIONS, there is probable cause to believe those records will be stored on that computer or storage medium, for at least the following reasons:

a. Based on my knowledge, training, and experience, I know that computer files or remnants of such files can be recovered months or even years after they have been downloaded onto a storage medium, deleted, or viewed via the Internet. Electronic files downloaded to a storage medium can be stored for years

at little or no cost. Even when files have been deleted, they can be recovered months or years later using forensic tools. This is so because when a person "deletes" a file on a computer, the data contained in the file does not actually disappear; rather, that data remains on the storage medium until it is overwritten by new data.

b. Therefore, deleted files, or remnants of deleted files, may reside in free space or slack space—that is, in space on the storage medium that is not currently being used by an active file—for long periods of time before they are overwritten. In addition, a computer's operating system may also keep a record of deleted data in a "swap" or "recovery" file.

c. Wholly apart from user-generated files, computer storage media—in particular, computers' internal hard drives—contain electronic evidence of how a computer has been used, what it has been used for, and who has used it. To give a few examples, this forensic evidence can take the form of operating system configurations, artifacts from operating system or application operation, file system data structures, and virtual memory "swap" or paging files. Computer users typically do not erase or delete this evidence, because special software is typically required for that task. However, it is technically possible to delete this information.

d. Similarly, files that have been viewed via the Internet are sometimes automatically downloaded into a temporary Internet directory or "cache."

e. Based on my experience and training, I know that individuals and businesses engaged in an income-producing business keep records of their financial activities. These records may be in the form of written notes and/or correspondence, receipts, negotiated instruments, bank statements, and other records. Records of this kind are most often stored on computers. In many instances, businesses use software based accounting applications to maintain their records.

f. Based on evidence related to this investigation, I am aware that computer equipment was used to generate, store, and print documents used in the criminal scheme. There is reason to believe that there is a computer system currently located at least some of the SUBJECT LOCATIONS.

43. *Forensic evidence.* As further described in Attachment B, this application seeks permission to locate not only computer files that might serve as direct evidence of the crimes described on the warrant, but also for forensic electronic evidence that establishes how computers were used, the purpose of their use, who used them, and when. There is probable cause to believe that this forensic

electronic evidence will be on any storage medium in the SUBJECT LOCATIONS because:

a. Data on the storage medium can provide evidence of a file that was once on the storage medium but has since been deleted or edited, or of a deleted portion of a file (such as a paragraph that has been deleted from a word processing file). Virtual memory paging systems can leave traces of information on the storage medium that show what tasks and processes were recently active. Web browsers, e-mail programs, and chat programs store configuration information on the storage medium that can reveal information such as online nicknames and passwords. Operating systems can record additional information, such as the attachment of peripherals, the attachment of USB flash storage devices or other external storage media, and the times the computer was in use. Computer file systems can record information about the dates files were created and the sequence in which they were created, although this information can later be falsified.

b. Forensic evidence on a computer or storage medium can also indicate who has used or controlled the computer or storage medium. This "user attribution" evidence is analogous to the search for "indicia of occupancy" while executing a search warrant at a residence. For example, registry information, configuration files, user profiles, e-mail, e-mail address books, "chat," instant messaging logs, photographs, the presence or absence of malware, and

correspondence (and the data associated with the foregoing, such as file creation and last-accessed dates) may be evidence of who used or controlled the computer or storage medium at a relevant time.

c. A person with appropriate familiarity with how a computer works can, after examining this forensic evidence in its proper context, draw conclusions about how computers were used, the purpose of their use, who used them, and when.

d. The process of identifying the exact files, blocks, registry entries, logs, or other forms of forensic evidence on a storage medium that are necessary to draw an accurate conclusion is a dynamic process. While it is possible to specify in advance the records to be sought, computer evidence is not always data that can be merely reviewed by a review team and passed along to investigators. Whether data stored on a computer is evidence may depend on other information stored on the computer and the application of knowledge about how a computer behaves. Therefore, contextual information necessary to understand other evidence also falls within the scope of the warrant.

e. Further, in finding evidence of how a computer was used, the purpose of its use, who used it, and when, sometimes it is necessary to establish that a particular thing is not present on a storage medium. For example, the presence or

absence of counter-forensic programs or anti-virus programs (and associated data) may be relevant to establishing the user's intent.

44. *Necessity of seizing or copying entire computers or storage media.* In most cases, a thorough search of a premises for information that might be stored on storage media often requires the seizure of the physical storage media and later off-site review consistent with the warrant. In lieu of removing storage media from the premises, it is sometimes possible to make an image copy of storage media. Generally speaking, imaging is the taking of a complete electronic picture of the computer's data, including all hidden sectors and deleted files. Either seizure or imaging is often necessary to ensure the accuracy and completeness of data recorded on the storage media, and to prevent the loss of the data either from accidental or intentional destruction. This is true because of the following:

a. *The time required for an examination.* As noted above, not all evidence takes the form of documents and files that can be easily viewed on site. Analyzing evidence of how a computer has been used, what it has been used for, and who has used it requires considerable time, and taking that much time on premises could be unreasonable. As explained above, because the warrant calls for forensic electronic evidence, it is exceedingly likely that it will be necessary to thoroughly examine storage media to obtain evidence. Storage media can store a large volume of information. Reviewing that information for things described in

the warrant can take weeks or months, depending on the volume of data stored, and would be impractical and invasive to attempt on-site.

b. *Technical requirements*. Computers can be configured in several different ways, featuring a variety of different operating systems, application software, and configurations. Therefore, searching them sometimes requires tools or knowledge that might not be present on the search site. The vast array of computer hardware and software available makes it difficult to know before a search what tools or knowledge will be required to analyze the system and its data on the Premises. However, taking the storage media off-site and reviewing it in a controlled environment will allow its examination with the proper tools and knowledge.

c. *Variety of forms of electronic media*. Records sought under this warrant could be stored in a variety of storage media formats that may require off-site reviewing with specialized forensic tools.

45. *Nature of examination*. Based on the foregoing, and consistent with Rule 41(e)(2)(B), the warrant I am applying for would permit seizing, imaging, or otherwise copying storage media that reasonably appear to contain some or all of the evidence described in the warrant, and would authorize a later review of the media or information consistent with the warrant. The later review may require

techniques, including but not limited to computer-assisted scans of the entire medium, that might expose many parts of a hard drive to human inspection in order to determine whether it is evidence described by the warrant.

CONCLUSION

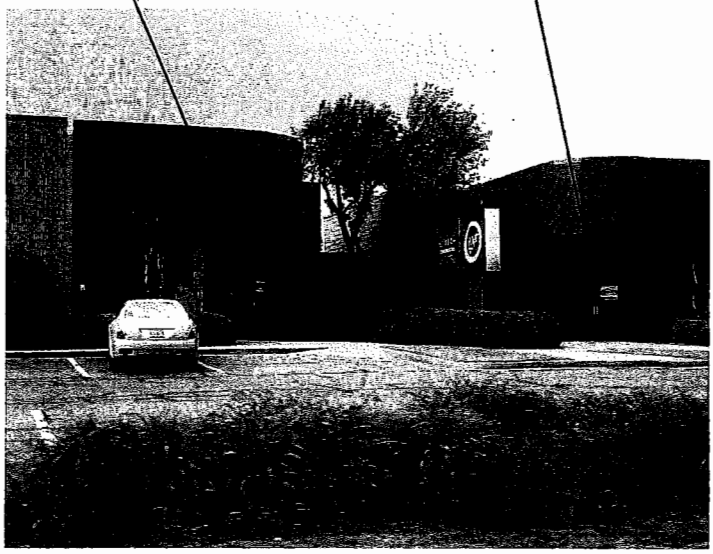
46. Based on the foregoing, I believe there is probable cause to believe that Hi-Tech is committing violations of federal law, including violations of: (a) Title 21, United States Code, Sections 331(a) and 333(a)(2) (introducing or delivering for introduction into interstate commerce misbranded foods and/or drugs); (b) Title 21, United States Code, Sections 331(k) and 333(a)(2) (doing an act to a food and/or drug after shipment in interstate commerce and while held for sale that results in the food and/or drug being misbranded); and (c) Title 21, United States Code, Section 841(a)(1) (manufacturing and distributing controlled substances). Furthermore, I have probable cause to believe that evidence of the type described in Attachment B to this Affidavit, which constitutes evidence of the aforementioned federal violations is currently located at the SUBJECT LOCATIONS.

ATTACHMENT A-1

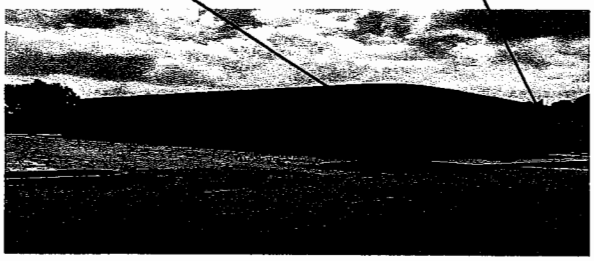
SUBJECT LOCATION 1, a business property located at 6015 Unity Drive, Suites A, B, D and F Norcross, GA 30071. A picture of the location is incorporated herein.

Front View

Suite B Suite D



Suite F Suite A



Suite A is located within the business complex of 6015 Unity Drive. The front door to Suite A is located on the northwest side of the building (on the back side of Suite B) and has glass doors with no descriptive markings. Suite F is located within the business complex of 6015 Unity Drive. The front door to Suite F is located on the northeast side of the building (on the backside of Suite D) and contains a green in color sign on the door marked as 6015-F.

ATTACHMENT B

Evidence, fruits, and instrumentalities of violations of federal law, including 21 U.S.C. § 331 and 21 U.S.C. § 841(a)(1). This evidence, fruits, and instrumentalities include:

1. Any misbranded and/or adulterated foods and/or drugs, including but not limited to products purportedly labeled as dietary supplements.

2. Any Schedule III controlled substances in whatever form present.

3. Raw materials and bulk powders used to distribute controlled substances and/or manufacture misbranded and/or adulterated foods and/or drugs.

4. All labels, labeling, and advertisements pertaining to misbranded and/or adulterated foods and/or drugs, including magazines, videotapes, handouts, inserts, flyers, and other promotional material.

5. Paraphernalia for manufacturing, packaging, weighing, or distributing controlled substances or misbranded and/or adulterated foods and/or drugs.

6. All electronic devices, including but not limited to, computers, routers, modems, hard drives, flash drives, cell phones, printers and label making

devices utilized in any capacity involving the manufacturing or distribution of controlled substances and/or adulterated foods and/or drugs.

7. All business records and related correspondence, in whatever form, including handwritten and computer-generated, pertaining to the illegal purchase, possession, and/or unauthorized distribution of controlled substances and introduction into interstate commerce any misbranded and/or adulterated foods and/or drugs. The documents to be seized include those relating to the brokering, ordering, producing, purchasing, shipping, selling and distributing of misbranded and/or adulterated foods and/or drugs, including but not limited to: business journals and ledgers; purchase orders; invoices; contracts; receipts; delivery receipts; work orders; production records, batch records, recipes, product formulations, laboratory test results, certificates of content, certificates of analysis, certificates of free sale, GMP certifications, GMP audit reports, telephone, telefax, and computer Internet records; written and electronic correspondence; bank records, including bank statements; records of investment accounts; financial statements and summaries; letters of credit; canceled checks, check registers, and other records reflecting payments; airway bills; bills of lading; handwritten notes; memoranda; address books; sales orders; purchase orders; rolodexes, business cards, and other documents identifying suppliers and customers; shippers' letters of instructions; business inquiries;

confirmations; commodity business brochures; supplier and customer lists; records of purchase from suppliers; application forms, documents, and literature regarding the FDA and/or State agency; and any unopened mail addressed to or from the individuals/businesses mentioned herein.

8. All tax records, including summaries and schedules.

9. All records relating to property, both real and personal, that may have been acquired with the proceeds of the illegal purchase, possession, and unauthorized distribution of controlled substances or introduction into interstate commerce of any misbranded and/or adulterated foods and/or drugs.

10. Indicia of occupancy, residency, and/or ownership of the premises to be searched.

11. Relating to computer-generated records, such records include:

    A. Any and all information and/or data stored in the form of magnetic or electronic coding on computer media or on media capable of being read by a computer or with the aid of computer-related equipment. This media includes floppy diskettes, fixed hard disks, removable hard disk cartridges, tapes, laser discs, video cassettes and other media that is capable of storing

magnetic coding, as well as punch cards, and/or paper tapes, and all printouts of stored data.

B. Any and all electronic devices that are capable of analyzing, creating, displaying, converting or transmitting electronic or magnetic computer impulses or data. These devices include computers, computer components, computer peripherals, word-processing equipment, modems, monitors, cables, printers, plotters, encryption circuit boards, optical scanners, external hard drives, external tape backup drives and other computer-related electronic devices.

C. Any and all instructions or programs stored in the form of electronic or magnetic media that are capable of being interpreted by a computer or related components. The items to be seized include operating systems, application software, utility programs, compilers, interpreters and other programs or software used to communicate with computer hardware or peripherals either directly or indirectly via telephone lines, radio or other means of transmission.

D. Any and all written or printed material that provides instruction or examples concerning the operation of computer systems or software, and/or any related device, and sign-on passwords, encryption codes or other information needed to access the computer system and/or software programs.

The terms "items," "records" and "documents" include all of the foregoing items of evidence in whatever form and by whatever means such items, records, or documents, their drafts, or their modifications may have been created or stored, including (but not limited to) any handmade form (such as writing, drawing, painting, with any implement on any surface, directly or indirectly); any photographic form (such as microfilm, microfiche, prints, slides, negatives, videotapes, motion pictures, photocopies); any mechanical form (such as phonographic records, printing, or typing); and electronic or magnetic form (such as tape recordings, cassettes, compact discs, or any information on an electronic or magnetic storage device, such as floppy diskettes, hard disks, backup tapes, optical discs, printer buffers, smart cards, memory calculators, electronic dialers, or electronic notebooks, as well as printouts or readouts from any magnetic storage device).

In order to search for data that is capable of being read or interpreted by a computer, law enforcement personnel may need to seize and search the following items:

a. Any computer equipment and storage device capable of being used to commit, further or store evidence of crimes, including but not limited to the introduction into interstate commerce of misbranded and/or

adulterated foods and/or drugs in violation to Title 21 USC § 331, and manufacturing and distributing controlled substances in violation of 21 USC § 841(a)(1).

b. Any computer equipment used to facilitate the transmission, creation, display, encoding or storage of data, including word processing equipment, modems, docking stations, monitors, printers, plotters, encryption devices, and optical scanners;

c. Any magnetic, electronic or optical storage device capable of storing data, such as floppy disks, hard disks, tapes, CD-ROMs, CD-R, CD-RWs, DVDs, optical disks, printer or memory buffers, smart cards, PC cards, memory calculators, electronic dialers, electronic notebooks, and personal digital assistants;

d. Any documentation, operating logs and reference manuals regarding the operation of the computer equipment, storage devices or software;

e. Any applications, utility programs, compilers, interpreters, and other software used to facilitate direct or indirect communication with the computer hardware, storage devices or data to be searched;

f. Any physical keys, encryption devices, dongles and similar physical items that are necessary to gain access to the computer equipment, storage devices

or data; and

g. Any passwords, password files, test keys, encryption codes or other information necessary to access the computer equipment, storage devices or data.

In addition, agents conducting this search are authorized to utilize the service(s) of outside computer expert(s), who may not be Federal Law Enforcement Officer(s), in order to use and operate the computer system(s) at the above specified location(s), for purposes of retrieving the above specified computer information during the course of the authorized search, provided that such expert(s) operate under the direction, supervision, and control of Special Agent(s) of the United States Food and Drug Administration Office of Criminal Investigations.

As used above, the terms "records" and "information" includes all forms of creation or storage, including any form of computer or electronic storage (such as hard disks or other media that can store data); any handmade form (such as writing); any mechanical form (such as printing or typing); and any photographic form (such as microfilm, microfiche, prints, slides, negatives, videotapes, motion pictures, or photocopies).

The term "computer" includes all types of electronic, magnetic, optical, electrochemical, or other high speed data processing devices performing logical, arithmetic, or storage functions, including desktop computers, notebook computers, mobile phones, tablets, server computers, and network hardware.

The term "storage medium" includes any physical object upon which computer data can be recorded. Examples include hard disks, RAM, floppy disks, flash memory, CD-ROMs, and other magnetic or optical media.

Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA, Plaintiff,	:	
v.	:	CIVIL ACTION NO. 1:13-CV-3675-WBH
QUANTITIES OF FINISHED AND IN-PROCESS FOODS, et al., Defendants.	:	

ORDER

Hi-Tech Pharmaceuticals, Inc., sells dietary supplements, including weight loss products containing 1, 3 Dimethylamylamine, commonly known as DMAA. The Federal Food and Drug Administration, contending that DMAA is a food additive that is not generally recognized as safe and that products containing DMAA are subject to seizure under federal law, seized a great deal of Hi-Tech's product and initiated this in rem forfeiture action. In response, Hi-Tech and its CEO entered the forfeiture action as claimants, contending that its DMAA products were not subject to seizure under the law and demanded that the Government[1] return Hi-Tech's products. Hi-Tech also filed suit against the Government, which action was merged into this forfeiture action.

[1] Hereinafter, "Hi-Tech" refers to both Hi-Tech and Jared Wheat. "The Government" refers to the FDA, the Commissioner of the FDA, and any other federal entities or individuals involved in this case.

Both sides have now filed motions for summary judgment, and this Court now considers those motions.

Discussion

Summary judgment is appropriate where "'there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law.'" Wooden v. Bd. of Regents of the Univ. Sys. of Ga., 247 F.3d 1262, 1271 (11th Cir. 2001) (quoting Fed. R. Civ. P. 56(c)).

The Federal Food, Drug, and Cosmetic Act and the Dietary Supplement Health and Education Act

The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., is a set of laws dating to 1938 that give authority to the FDA to oversee and regulate the safety of food, drugs, and cosmetics. The Dietary Supplement Health and Education Act of 1994 (DSHEA) amended the FDCA to require the FDA to characterize dietary supplements as food rather than drugs. Further, while the FDA may still establish standards for dietary supplements, the DSHEA shifted the burden of proof to the Government to have a dietary supplement declared unsafe and removed from commerce.

Under the DSHEA, this Court must first determine whether DMAA is a "dietary ingredient" or a "food additive." 21 U.S.C. § 321(s), (ff). If DMAA is determined to be a dietary ingredient, the seized Hi-Tech products qualify as dietary supplements which cannot be removed from commerce by the Government unless the FDA establishes that it "presents a significant or unreasonable risk of illness or injury under . . . conditions of use recommended or suggested in labeling," and this Court so finds "on a *de novo* basis." 21 U.S.C. § 342(f).

If the substance is determined not to be a dietary ingredient, then this Court must determine whether that substance is "generally recognized as safe." Id. § 321(s). If the substance is not generally recognized as safe, it is a food additive and presumed to be unsafe so that any supplements containing that substance are adulterated under the statute.

Whether DMAA is a Dietary Ingredient

Relevant to this case, dietary ingredients include "an herb or other botanical . . . or a concentrate, metabolite, constituent, extract, or combination of" an herb or other botanical. 21 U.S.C. § 321(ff). Accordingly, the first issue that must be determined under the statutory scheme is whether DMAA is a "botanical" as that word is used in

the statute. The Government stipulates that it bears the burden of proving that DMAA is not a botanical.

Nothing in the legislative history of the DSHEA or in the case law gives any guidance regarding what Congress meant by "botanical" in § 321(ff). Hi-Tech does not provide a definition of a botanical under the statute in its summary judgment motion. The Government asserts that a botanical is "a plant, alga, or fungus, or a physical part or secretion of a plant, alga, or fungus, such as bark, leaves or fruits." In support of this assertion, the Government cites to the affidavit of its expert, Cara Welch. In her affidavit, Dr. Welch gives generally the same definition of a botanical and cites to her report. Dr. Welch's report gives that same definition for botanical and cites to an online FDA publication[2] that gives the same definition in its glossary without citation to anything. The FDA publication merely purports to provide guidance to industry regarding the requirements of providing notice to the FDA relating to new dietary ingredients. The publication does not appear to be a scientific paper and there is no indication of who wrote it. In short, the Government has failed to provide an adequate basis for its interpretation of Congressional intent in using the term "botanical" in § 321(ff). This Court thus finds that the Government's definition

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[2] *Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry*, available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM515733.pdf

is arbitrary and not entitled to deference under Chevron, U.S.A., Inc. v. Nat. Resources Def. Council, Inc., 467 U.S. 837 (1984).

Hi-Tech has presented fairly substantial evidence that trace amounts of DMAA have been found in a species of a geranium plant in the form of three published papers that provided the details of tests detecting DMAA. The Government has asserted three arguments to dispute the presence of DMAA in geraniums, but this Court finds that those arguments are not sufficient to meet the Government's burden of establishing that DMAA is not in geraniums. This Court is first unimpressed by the Government's arguments regarding the fact that other studies have failed to find the presence of DMAA in geraniums. In particular, this Court takes judicial notice of a paper, Thomas D. Gauthier, *Evidence for the Presence of 1,3-Dimethylamylamine (1,3-DMAA) in Geranium Plant Materials*, ANALYTICAL CHEMICAL INSIGHTS, 8: 29-40 (2013) available at https://www.ncbi.nlm.nih.gov/ pmc/articles/PMC3682735/, in which the author surveyed the various studies that either found or did not find DMAA in geranium plants. He concluded that, "[o]verall, these studies show that 1,3-DMAA is found naturally in some, but not all, geranium plants and extracted geranium oils." The author further opined that the studies that failed to find DMAA used extraction techniques that may not have been suitable for retention of DMAA due to its volatility. It is undisputed that at least three different studies found DMAA in geraniums, and the

fact that other studies, which may well have used different methodologies, did not detect DMAA is not determinative.

This Court is likewise unswayed by the Government's argument that it is impossible for the geranium in question to synthesize DMAA. In its motion for summary judgment, the Government asserts that: "The uncontroverted evidence is clear: Geraniums cannot make DMAA. There is no biological process or biosynthetic pathway by which a geranium plant could do so." However, the expert that the Government cites for this statement is nowhere near as unequivocal. Rather, she states that it is "metabolically improbable" that DMAA naturally occurs in geranium plants, and points out that "[t]hose suggesting [DMAA] is naturally occurring in [geraniums] have not proposed a biosynthetic pathway by which the compound could be produced nor provided any evidence that such a pathway exists," [Doc. 113-1 at 29, 27], which is nothing close to uncontroverted evidence that geraniums cannot make DMAA. Further, the question as presented by the parties is whether DMAA has been detected in geraniums, not how the geraniums happened to put the chemical there.

Finally, in response to the Government's argument that the geraniums from one of the studies may have been contaminated by fertilizer that contained DMAA, the argument fails to address the fact that other studies did find DMAA.

Admittedly, there are reasons to doubt the veracity of the studies that detected DMAA in geraniums given the questions raised by the Government and the fact that the amounts found were so small. In addition, at least some of the studies upon which Hi-Tech relies were sponsored by companies in the supplement industry, and while this Court has no basis upon which to question the earnestness of the authors of those studies, it is no secret that scientific studies performed on behalf of industry tend to produce the results that industry wants to see. Nonetheless, this Court would be inclined to find that the Government has failed to meet its burden of establishing that DMAA has not been found in geraniums. That, however, does not end the inquiry in this Court's opinion. As mentioned, if DMAA is in geraniums, it exists there in only trace amounts. The Gauthier article cited above indicated that the studies that detected DMAA generally found concentrations of less than 500 parts per billion, and while one sample was as high as 13 parts per million, that is still a minuscule amount. It is significant to this Court that, while studies might have found the presence of DMAA in geraniums, no one has ever extracted DMAA from geraniums for any commercial, medicinal or other purpose. It has merely been detected.

This Court returns to the topic of Congress' intent in using the word botanical in 21 U.S.C. § 321(ff), having determined that the Government's definition is not entitled to Chevron deference. In normal usage, a botanical is a plant, a part of a plant,

or a substance that is derived from a plant for a medicinal, cosmetic, or other purpose. Oxford Dictionary defines botanical as "[a] substance obtained from a plant and used as an additive, especially in gin or cosmetics," available at https://en.oxford dictionaries.com/definition/us/botanical, while the web sight Dictionary.com defines it as "a drug made from part of a plant, as from roots, leaves, bark, or berries," available at http://www.dictionary.com/ browse/botanical. The clear implication is that to be a botanical, the substance must have been extracted from a plant or plant-like organism and used, for example, in or as a medicine. While very small amounts of DMAA might be present in geraniums, the DMAA in the marketplace has *never* been extracted from geraniums or any other plant.

This Court credits Hi-Tech's argument that a botanical can be synthesized in a laboratory without losing its status as a botanical under § 321(ff). Indeed, growing popularity of a substance in a certain plant might endanger that plant's existence if manufacturers were not permitted to synthesize the substance without running afoul of the requirements in the DSHEA, and chemical synthesis is often more economically efficient than extracting a particular compound from a plant. Nonetheless, it is inconceivable that in passing the DSHEA Congress intended for supplement manufacturers to take a chemical that heretofore had only been manufactured in a laboratory and to scour the globe in search of minuscule amounts of that chemical in

obscure plants so that they could declare the substance a dietary ingredient under the statute. To hold otherwise would be to open the door to bogus claims that, for example, a given chemical had been detected in a fungus found only in a remote Tibetan river valley, and the FDA would be left to refute that claim – to prove a negative – which the instant case demonstrates is not easily done.

This Court thus concludes that in using the term botanical, Congress intended that there must be at least some history of the substance in question having been extracted in usable quantities from a plant or a plant-like organism, leading this Court to find that DMAA is not a botanical and thus not a dietary ingredient.

Accordingly, with one possible exception discussed below, DMAA is a "food additive." Relevant to this case, a food additive is presumed unsafe unless "there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used." 21 U.S.C. § 348(a)(2). There is no such regulation.

The one possible exception is under 21 U.S.C. § 321(s), pursuant to which the FDCA exempts from the definition of "food additive" foods that are "generally recognized . . . as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe." This status is

referred to as "Generally Recognized as Safe" or "GRAS." Substances that are GRAS may be used in food without FDA approval or review. 21 U.S.C. §§ 321(s), 348(b). The burden of establishing that DMAA is GRAS rests with Hi-Tech.

As DMAA was not used in food prior to 1958, for it to be GRAS, Hi-Tech must demonstrate "both technical evidence of safety and a basis to conclude that this technical evidence of safety is generally known and accepted" among the scientific community. 62 Fed.Reg. 18940 (explaining the requirements of 21 C.F.R. § 170.30(a–b)); see United States v. Western Serum Co., Inc., 666 F.2d 335, 338 (9th Cir. 1982); United States v. Articles of . . . Promise Toothpaste, 624 F. Supp. 776, 778 (N.D. Ill. 1985), *aff'd* 826 F.2d 564 (7th Cir. 1987); United States v. Articles of Drug . . . Hormonin, 498 F. Supp. 424, 435 (D.N.J. 1980). Although unanimity among scientists is not required, there must be a general consensus regarding the safety of the substance in question for it to be considered GRAS. U.S. v. BioAnue Laboratories, Inc., 2014 WL 3696662 at *7 (M.D. Ga. July 23, 2014); see United States v. An Article of Food, 752 F.2d 11, 15 n.6 (1st Cir. 1985) (noting that evidence of a "genuine dispute among qualified experts" is "sufficient to preclude a finding of 'general recognition' of safe use").

Both sides of this dispute have presented extensive documentation regarding DMAA and the studies that have been performed on the effects of DMAA on humans

and animals. This Court's conclusion after reading the various expert reports and other documents is that there is no consensus regarding the question of whether the consumption of DMAA is safe.

This Court will avoid engaging in a detailed review of the numerous studies identified and discussed by the parties' experts. However, United States Magistrate Judge Anne T. Berton, in ruling on a Daubert motion in a DMAA products liability case in Texas, provided an exhaustive discussion of the various available studies of the effects of DMAA and noted that "[i]t is clear . . . that the scientific literature on DMAA presents insufficient data to conclude that DMAA is safe or that DMAA causes harm because the sample sizes are too small." Sparling v. Doyle, 2015 WL 4528759 at *35 (W.D. Tex. July 27, 2015).

This Court further notes that scientists have raised legitimate concerns regarding the safety of DMAA. DMAA is chemically similar to amphetamine, and some scientists have concerns that DMAA may have some of that drug's negative effects. The Government's expert, Dr. Dennis M. Keefe identified "[e]leven articles [that] described case reports or clinical studies involving adverse outcomes that occurred after the consumption of DMAA-containing products." [Doc. 107-8 at 33]. Five reports associated recreational DMAA consumption with substance abuse, [id.], three

studies identified liver toxicity, [id.], and several studies showed elevated blood pressure, [id. at 34].

To be sure, Hi-Tech has presented the results of studies that show no adverse (or no significant adverse) effect from DMAA. However, as the Government's expert points out, and as echoed by Magistrate Judge Berton, the sample sizes of those studies is simply too small to provide any convincing evidence regarding the safety of DMAA. Moreover, the safety of DMAA is not really the issue, and it does not matter that concerns about DMAA may be unfounded. The question is whether there is a consensus among experts regarding DMAA's safety, and this Court concludes that Hi-Tech has failed to present sufficient evidence to demonstrate that consensus, leading to the further conclusion that DMAA is not generally recognized as safe under the FDCA. Accordingly, products for human consumption containing DMAA are adulterated foods under the FDCA and subject to seizure pursuant to 21 U.S.C. § 334.

This Court's determination that Hi-Tech's products containing DMAA are subject to seizure and forfeiture necessarily requires this Court to further conclude that the officials involved in the seizure and sued by Hi-Tech did not violate the FDCA, the DSHEA, the Administrative Procedures Act (5 U.S.C. § 702), or the Due Process Clause of the Fifth Amendment to the United States Constitution as claimed by Hi-

Tech in the suit originally filed in Washington, D.C., and ultimately merged into this action.

Conclusion

For the reasons discussed, the Government's motion for summary judgment, [Doc. 107], is **GRANTED** and Hi-Tech's motion for summary judgment, [Doc. 108], is **DENIED**. The Clerk is **DIRECTED** to enter judgment as to all claims in favor of the Government and against the Defendants undetermined quantities of all articles of finished and in-process foods, raw ingredients (bulk powders, bulk capsules) containing DMAA with any lot number, size, or type container, whether labeled or unlabeled as listed in the amended complaint, [Doc. 25 as further amended by Doc. 138], and also against Claimants Hi-Tech Pharmaceuticals, Inc., and Jared Wheat in the forfeiture action. The Clerk is further **DIRECTED** to enter judgment as to all claims in favor of Defendants and against Plaintiffs in the suit originally filed in the District Court for the District of Columbia, Hi-Tech Pharmaceuticals, Inc. v. FDA, et al., No. 1:13-CV-1747 (D.D.C.), later transferred to this Court as Hi-Tech Pharmaceuticals, Inc. v. FDA, et al., 1:14-CV-2479 (N.D. Ga.), and even later merged into this action.

The Defendants in the forfeiture action, undetermined quantities of all articles of finished and in-process foods, raw ingredients (bulk powders, bulk capsules) containing DMAA with any lot number, size, or type container, whether labeled or unlabeled listed in the amended complaint, [Doc. 25 as further amended by Doc. 138], are hereby **CONDEMNED**, and **FORFEITED** to the United States for destruction.

As this Court did not rely on the testimony of Iklas A. Khan, James P. Kababick, Rick Flurer, or Paula N. Brown, Hi-Tech's motions to strike their testimony, [Docs. 91, 100, 101, 102, 103, 122], are **DENIED** as moot.

The parties' various motions to seal documents, [Docs. 99, 105, 111, 112, 114], and to file excess pages, [Docs. 106, 110, 118], are **GRANTED** nunc pro tunc.

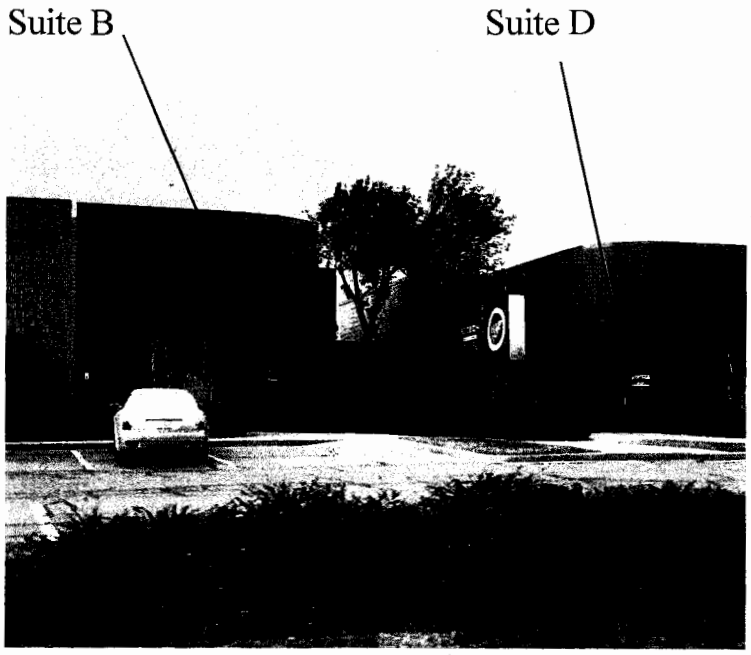
IT IS SO ORDERED, this 3rd day of April, 2017.

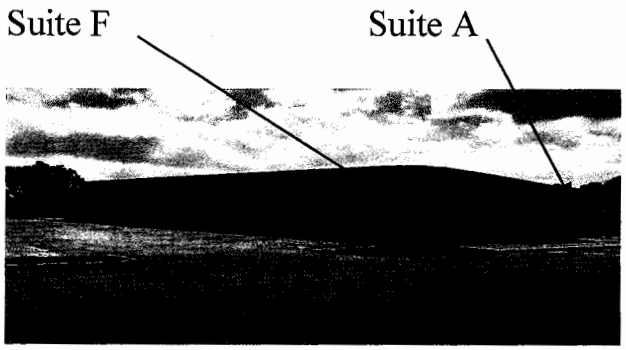
WILLIS B. HUNT, JR.
Judge, U. S. District Court

ATTACHMENT A-1

SUBJECT LOCATION 1, a business property located at 6015 Unity Drive, Suites A, B, D and F Norcross, GA 30071. A picture of the location is incorporated herein.

Front View





Suite A is located within the business complex of 6015 Unity Drive. The front door to Suite A is located on the northwest side of the building (on the back side of Suite B) and has glass doors with no descriptive markings. Suite F is located within the business complex of 6015 Unity Drive. The front door to Suite F is located on the northeast side of the building (on the backside of Suite D) and contains a green in color sign on the door marked as 6015-F.

ATTACHMENT B

Evidence, fruits, and instrumentalities of violations of federal law, including Title 21, United States Code, Section 331(a) and (k). This evidence, fruits, and instrumentalities include:

1. Any finished or in-process dietary supplements and/or food containing or labeled as containing DMAA or its chemical equivalent.

2. Raw materials, ingredients, and/or bulk powders containing or labeled as containing DMAA or its chemical equivalent.

3. All labels, labeling, and advertisements pertaining to dietary supplements and/or food containing or labeled as containing DMAA or its chemical equivalent, including magazines, videotapes, handouts, inserts, flyers, and other promotional material.

4. Paraphernalia for manufacturing, packaging, weighing, or distributing dietary supplements and/or food containing or labeled as containing DMAA or its chemical equivalent.