

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

UNITED STATES OF AMERICA)	
)	
Plaintiff,)	CIVIL CASE NO.
)	
v.)	
)	
Undetermined quantities of all)	
articles of finished and in-process)	
foods, raw ingredients (bulk powders,)	
bulk capsules) listed below, with any)	
lot number, size, or type container,)	
whether labeled or unlabeled:)	
)	
Black Widow)	
ECA XTREME)	
FASTIN)	
FASTIN-XR)	
FASTIN powder)	
FASTIN-XR bulk capsules)	
Geranium Powder)	
Lipodrene)	
Lipodrene HARDCORE)	
Lipodrene HARDCORE bulk capsules)	
Lipodrene XR)	
Lipodrene XTREME)	
LIPOTHERM)	
Methylhexamine)	
Natural Geranium Powder 25%)	
Stimerex-ES)	
YELLOW SCORPION)	
YELLOW SCORPION bulk capsules)	
YELLOW SCORPION powder)	
)	
and)	
)	
all articles of finished and in-)	
process foods, raw ingredients (bulk)	
powders, bulk capsules), containing)	
1,3-Dimethylamylamine HCl(DMAA)or its))	
chemical equivalent, with any lot)	
number, size, or type container,)	
whether labeled or unlabeled which)	
are determined to consist in whole)	
or in part of components, by their)	
labeling or otherwise, to have)	

originated outside the State of)
 Georgia, and are located anywhere on)
 the premises of Hi-Tech)
 Pharmaceuticals, Inc. 5440 Oakbrook)
 Parkway, Suite A, Norcross, Georgia,)
 or elsewhere within the jurisdiction)
 of this Court.)
)
)
)
 Defendants.)

COMPLAINT FOR FORFEITURE

NOW COMES the United States of America, Sally Quillian Yates, United States Attorney for the Northern District of Georgia, and Jenny R. Turner, Assistant United States Attorney for said District, respectfully state as follows:

NATURE OF ACTION

1. That this complaint is filed by the United States of America, and requests seizure and condemnation of articles of food as described in the caption, in accordance with the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq.

JURISDICTION AND VENUE

2. That this court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334.

3. That there are at Norcross, Georgia in the possession of Hi-Tech Pharmaceuticals, Inc., 540 Oakbrook Parkway, Suite

A, or elsewhere within the jurisdiction of this Court, articles which are foods within the meaning of 21 U.S.C. § 321(ff), which consist in whole or in part of ingredients that were shipped in interstate commerce from outside the State of Georgia.

4. That this Court has in rem jurisdiction over the articles, because they are located in the Northern District of Georgia.

BASIS FOR FORFEITURE

5. That the articles of food are adulterated after receipt in interstate commerce and while held for sale, within the meaning of the Act, 21 U.S.C. 342(a)(2)(C)(i), in that they contain the food additive DMAA or its chemical equivalent, which is unsafe within the meaning of 21 U.S.C. § 348.
6. That by reason of the foregoing, the articles are held illegally within the jurisdiction of this Court and are liable to seizure, condemnation, and forfeiture pursuant to 21 U.S.C. § 334.

FACTS

7. United States Food and Drug Administration (FDA) investigators initiated an inspection of Hi-Tech Pharmaceuticals, Inc. on October 24, 2013. During the

inspection, the investigators identified the following eleven products that were labeled as containing 1,3-Dimethylamylamine ("DMAA") or its chemical equivalent: Black Widow, ECA XTREME, FASTIN, FASTIN-XR, Lipodrene, Lipodrene HARDCORE, Lipodrene XR, Lipodrene XTREME, LIPOTHERM, Stimerex-ES, and YELLOW SCORPION. The investigators also observed bulk DMAA raw ingredients. All finished products labeled as containing DMAA or its chemical equivalent; all unlabeled, in-process material; and bulk raw ingredients were inventoried and placed under administrative detention (Order DO 0041) which was executed on November 1, 2013. The investigators collected physical samples of the detained products, photographed product containers and cases, and collected limited interstate shipping records.

8. All articles of food located anywhere at Hi-Tech Pharmaceuticals, Inc., labeled or identified as containing the ingredient DMAA or its chemical equivalent, are adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i).
9. Under 21 U.S.C. § 321(s), a substance intended to become a component of food is a food additive, unless (1) it is

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; (2) it is subject to prior sanction; or (3) it is an ingredient described in 21 U.S.C. § 321(ff) (a dietary ingredient). The other exceptions listed in 21 U.S.C. § 321(s) do not apply.

10. DMAA is not a dietary ingredient, because it does not meet any of the elements in 21 U.S.C. § 321(ff)(1).
11. DMAA is not generally recognized as safe under the conditions of use in these products. DMAA does not satisfy the second exception because it is not the subject of a sanction or approval pursuant to the Act, or the other statutes identified in 21 U.S.C. § 321(s). DMAA is, therefore, a food additive.
12. Under 21 U.S.C. § 348(a), a food additive is deemed unsafe unless it is used in conformity with a regulation prescribing conditions under which it may be safely used, it has been granted an exception for investigational use under 21 U.S.C. § 348(j), or it is a food contact substance. DMAA is not a food contact substance, there is no regulation prescribing the conditions under which DMAA

may be safely used, and no exemption for investigational use has been granted under 21 U.S.C. § 348(j). Therefore, DMAA is deemed unsafe under 21 U.S.C. § 348 and, the defendant Articles containing DMAA or its chemical equivalent are deemed adulterated under 21 U.S.C. § 342(a)(2)(C)(i).

13. By reason of the forgoing, the articles of food are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334.

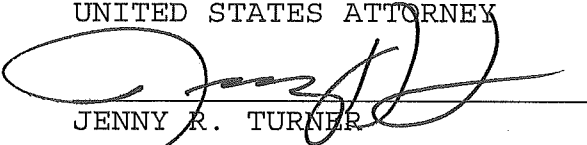
WHEREFORE, the United States of America prays that:

- (a). a warrant of arrest issue for all articles of food as described in the caption that are located at Hi-Tech Pharmaceuticals, Norcross, Georgia;
- (b). condemnation and judgment be entered declaring the defendant articles of food be forfeited to the United States of America and grant plaintiff the costs of this proceeding against the claimant of the articles;
- (c). defendant articles be disposed of pursuant to the provisions of the Act;

(d). and the United States of America be granted such other and further relief that the Court deems just and proper.

Respectfully submitted,

SALLY QUILLIAN YATES
UNITED STATES ATTORNEY

A handwritten signature in black ink, appearing to read "Jenny R. Turner", is written over a horizontal line. The signature is stylized and cursive.

JENNY R. TURNER
ASSISTANT U.S. ATTORNEY
GEORGIA BAR NO. 719439
75 SPRING STREET, S.W.
SUITE 600
ATLANTA, GEORGIA 30303
(404) 581-6084 - PHONE
Jenny.turner@usdoj.gov

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

UNITED STATES OF AMERICA)	
)	
Plaintiff,)	CIVIL CASE NO.
v.)	
)	
Undetermined quantities of all)	
articles of finished and in-process)	
foods, raw ingredients (bulk powders,)	
bulk capsules) listed below, with any)	
lot number, size, or type container,)	
whether labeled or unlabeled:)	
et al.)	
)	
)	
Defendants.)	

VERIFICATION

I am Lakisha N. Morton, a Compliance Officer for the US Food and Drug Administration, United States Department of Health and Human Services, and I am familiar with the investigation of this case. I hereby verify and declare under penalty of perjury that I have read the foregoing Verified Complaint and know the contents thereof, and the matters contained in the Verified Complaint are true to my own knowledge.

The sources of my knowledge and information and the grounds of my belief are the official files and records of the FDA, as well as my investigation of this case.

I verify and declare under penalty of perjury that the foregoing is true and correct.

Executed on this 6th day of November, 2013.

A handwritten signature in black ink, appearing to read 'Lakisha N. Morton', written over a horizontal line.

Lakisha N. Morton
Compliance Officer
Food and Drug
Administration
Department of Health
and Human Services

JS44 (Rev. 1/13 NDGA)

CIVIL COVER SHEET

The JS44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form is required for the use of the Clerk of Court for the purpose of initiating the civil docket record. (SEE INSTRUCTIONS ATTACHED)

<p>I. (a) PLAINTIFF(S)</p> <p>UNITED STATES OF AMERICA</p> <p>(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF _____ <small>(EXCEPT IN U.S. PLAINTIFF CASES)</small></p>	<p>DEFENDANT(S)</p> <p>Undetermined quantities of all articles of finished and in-process foods, raw ingredients listed below, with any number, size, or type container, et al.</p> <p>COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____ <small>(IN U.S. PLAINTIFF CASES ONLY)</small></p> <p><small>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED</small></p>
<p>(c) ATTORNEYS (FIRM NAME, ADDRESS, TELEPHONE NUMBER, AND E-MAIL ADDRESS)</p> <p>JENNY R. TURNER Assistant U.S. Attorney 75 Spring Street, SW, Suite600 Atlanta, GA 30303 404-581-6084 jenny.turner@usdoj.gov</p>	<p>ATTORNEYS (IF KNOWN)</p>

<p>II. BASIS OF JURISDICTION <small>(PLACE AN "X" IN ONE BOX ONLY)</small></p> <p><input checked="" type="checkbox"/> 1 U.S. GOVERNMENT PLAINTIFF <input type="checkbox"/> 3 FEDERAL QUESTION (U.S. GOVERNMENT NOT A PARTY) <input type="checkbox"/> 2 U.S. GOVERNMENT DEFENDANT <input type="checkbox"/> 4 DIVERSITY (INDICATE CITIZENSHIP OF PARTIES IN ITEM III)</p>	<p>III. CITIZENSHIP OF PRINCIPAL PARTIES <small>(PLACE AN "X" IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) (FOR DIVERSITY CASES ONLY)</small></p> <table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><small>PLF</small></td> <td style="text-align: center;"><small>DEF</small></td> <td></td> <td style="text-align: center;"><small>PLF</small></td> <td style="text-align: center;"><small>DEF</small></td> <td></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td>CITIZEN OF THIS STATE</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> <td>INCORPORATED OR PRINCIPAL PLACE OF BUSINESS IN THIS STATE</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td>CITIZEN OF ANOTHER STATE</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> <td>INCORPORATED AND PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td>CITIZEN OR SUBJECT OF A FOREIGN COUNTRY</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> <td>FOREIGN NATION</td> </tr> </table>	<small>PLF</small>	<small>DEF</small>		<small>PLF</small>	<small>DEF</small>		<input type="checkbox"/> 1	<input type="checkbox"/> 1	CITIZEN OF THIS STATE	<input type="checkbox"/> 4	<input type="checkbox"/> 4	INCORPORATED OR PRINCIPAL PLACE OF BUSINESS IN THIS STATE	<input type="checkbox"/> 2	<input type="checkbox"/> 2	CITIZEN OF ANOTHER STATE	<input type="checkbox"/> 5	<input type="checkbox"/> 5	INCORPORATED AND PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE	<input type="checkbox"/> 3	<input type="checkbox"/> 3	CITIZEN OR SUBJECT OF A FOREIGN COUNTRY	<input type="checkbox"/> 6	<input type="checkbox"/> 6	FOREIGN NATION
<small>PLF</small>	<small>DEF</small>		<small>PLF</small>	<small>DEF</small>																					
<input type="checkbox"/> 1	<input type="checkbox"/> 1	CITIZEN OF THIS STATE	<input type="checkbox"/> 4	<input type="checkbox"/> 4	INCORPORATED OR PRINCIPAL PLACE OF BUSINESS IN THIS STATE																				
<input type="checkbox"/> 2	<input type="checkbox"/> 2	CITIZEN OF ANOTHER STATE	<input type="checkbox"/> 5	<input type="checkbox"/> 5	INCORPORATED AND PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE																				
<input type="checkbox"/> 3	<input type="checkbox"/> 3	CITIZEN OR SUBJECT OF A FOREIGN COUNTRY	<input type="checkbox"/> 6	<input type="checkbox"/> 6	FOREIGN NATION																				

IV. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

1 ORIGINAL PROCEEDING 2 REMOVED FROM STATE COURT 3 REMANDED FROM APPELLATE COURT 4 REINSTATED OR REOPENED 5 TRANSFERRED FROM ANOTHER DISTRICT (Specify District) 6 MULTIDISTRICT LITIGATION 7 APPEAL TO DISTRICT JUDGE FROM MAGISTRATE JUDGE JUDGMENT

V. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE - DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY)

21 U.S.C. 342 and 334: articles of food which are adulterated after receipt in interstate commerce and held illegally.

(IF COMPLEX, CHECK REASON BELOW)

<input type="checkbox"/> 1. Unusually large number of parties.	<input type="checkbox"/> 6. Problems locating or preserving evidence
<input type="checkbox"/> 2. Unusually large number of claims or defenses.	<input type="checkbox"/> 7. Pending parallel investigations or actions by government.
<input type="checkbox"/> 3. Factual issues are exceptionally complex	<input type="checkbox"/> 8. Multiple use of experts.
<input type="checkbox"/> 4. Greater than normal volume of evidence.	<input type="checkbox"/> 9. Need for discovery outside United States boundaries.
<input type="checkbox"/> 5. Extended discovery period is needed.	<input type="checkbox"/> 10. Existence of highly technical issues and proof.

CONTINUED ON REVERSE

FOR OFFICE USE ONLY			
RECEIPT # _____	AMOUNT \$ _____	APPLYING IFP _____	MAG. JUDGE (IFP) _____
JUDGE _____	MAG. JUDGE _____ <small>(Referral)</small>	NATURE OF SUIT _____	CAUSE OF ACTION _____

VI. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT - "0" MONTHS DISCOVERY TRACK

- 150 RECOVERY OF OVERPAYMENT & ENFORCEMENT OF JUDGMENT
- 152 RECOVERY OF DEFAULTED STUDENT LOANS (Excl. Veterans)
- 153 RECOVERY OF OVERPAYMENT OF VETERAN'S BENEFITS

CONTRACT - "4" MONTHS DISCOVERY TRACK

- 110 INSURANCE
- 120 MARINE
- 130 MILLER ACT
- 140 NEGOTIABLE INSTRUMENT
- 151 MEDICARE ACT
- 160 STOCKHOLDERS' SUITS
- 190 OTHER CONTRACT
- 195 CONTRACT PRODUCT LIABILITY
- 196 FRANCHISE

REAL PROPERTY - "4" MONTHS DISCOVERY TRACK

- 210 LAND CONDEMNATION
- 220 FORECLOSURE
- 230 RENT LEASE & EJECTMENT
- 240 TORTS TO LAND
- 245 TORT PRODUCT LIABILITY
- 290 ALL OTHER REAL PROPERTY

TORTS - PERSONAL INJURY - "4" MONTHS DISCOVERY TRACK

- 310 AIRPLANE
- 315 AIRPLANE PRODUCT LIABILITY
- 320 ASSAULT, LIBEL & SLANDER
- 330 FEDERAL EMPLOYERS' LIABILITY
- 340 MARINE
- 345 MARINE PRODUCT LIABILITY
- 350 MOTOR VEHICLE
- 355 MOTOR VEHICLE PRODUCT LIABILITY
- 360 OTHER PERSONAL INJURY
- 362 PERSONAL INJURY - MEDICAL MALPRACTICE
- 365 PERSONAL INJURY - PRODUCT LIABILITY
- 367 PERSONAL INJURY - HEALTH CARE/ PHARMACEUTICAL PRODUCT LIABILITY
- 368 ASBESTOS PERSONAL INJURY PRODUCT LIABILITY

TORTS - PERSONAL PROPERTY - "4" MONTHS DISCOVERY TRACK

- 370 OTHER FRAUD
- 371 TRUTH IN LENDING
- 380 OTHER PERSONAL PROPERTY DAMAGE
- 385 PROPERTY DAMAGE PRODUCT LIABILITY

BANKRUPTCY - "0" MONTHS DISCOVERY TRACK

- 422 APPEAL 28 USC 158
- 423 WITHDRAWAL 28 USC 157

CIVIL RIGHTS - "4" MONTHS DISCOVERY TRACK

- 441 VOTING
- 442 EMPLOYMENT
- 443 HOUSING/ ACCOMMODATIONS
- 444 WELFARE
- 440 OTHER CIVIL RIGHTS
- 445 AMERICANS with DISABILITIES - Employment
- 446 AMERICANS with DISABILITIES - Other
- 448 EDUCATION

IMMIGRATION - "0" MONTHS DISCOVERY TRACK

- 462 NATURALIZATION APPLICATION
- 465 OTHER IMMIGRATION ACTIONS

PRISONER PETITIONS - "0" MONTHS DISCOVERY TRACK

- 463 HABEAS CORPUS- Alien Detainee
- 510 MOTIONS TO VACATE SENTENCE
- 530 HABEAS CORPUS
- 535 HABEAS CORPUS DEATH PENALTY
- 540 MANDAMUS & OTHER
- 550 CIVIL RIGHTS - Filed Pro se
- 555 PRISON CONDITION(S) - Filed Pro se
- 560 CIVIL DETAINEE: CONDITIONS OF CONFINEMENT

PRISONER PETITIONS - "4" MONTHS DISCOVERY TRACK

- 550 CIVIL RIGHTS - Filed by Counsel
- 555 PRISON CONDITION(S) - Filed by Counsel

FORFEITURE/PENALTY - "4" MONTHS DISCOVERY TRACK

- 625 DRUG RELATED SEIZURE OF PROPERTY 21 USC 881
- 690 OTHER

LABOR - "4" MONTHS DISCOVERY TRACK

- 710 FAIR LABOR STANDARDS ACT
- 720 LABOR/MGMT. RELATIONS
- 740 RAILWAY LABOR ACT
- 751 FAMILY and MEDICAL LEAVE ACT
- 790 OTHER LABOR LITIGATION
- 791 EMPL. RET. INC. SECURITY ACT

PROPERTY RIGHTS - "4" MONTHS DISCOVERY TRACK

- 820 COPYRIGHTS
- 840 TRADEMARK

PROPERTY RIGHTS - "8" MONTHS DISCOVERY TRACK

- 830 PATENT

SOCIAL SECURITY - "0" MONTHS DISCOVERY TRACK

- 861 HIA (1395ff)
- 862 BLACK LUNG (923)
- 863 DIWC (405(g))
- 863 DIWW (405(g))
- 864 SSDI TITLE XVI
- 865 RSI (405(g))

FEDERAL TAX SUITS - "4" MONTHS DISCOVERY TRACK

- 870 TAXES (U.S. Plaintiff or Defendant)
- 871 IRS - THIRD PARTY 26 USC 7609

OTHER STATUTES - "4" MONTHS DISCOVERY TRACK

- 375 FALSE CLAIMS ACT
- 400 STATE REAPPORTMENT
- 430 BANKS AND BANKING
- 450 COMMERCE/ICC RATES/ETC.
- 460 DEPORTATION
- 470 RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS
- 480 CONSUMER CREDIT
- 490 CABLE/SATELLITE TV
- 891 AGRICULTURAL ACTS
- 893 ENVIRONMENTAL MATTERS
- 895 FREEDOM OF INFORMATION ACT
- 950 CONSTITUTIONALITY OF STATE STATUTES
- 890 OTHER STATUTORY ACTIONS
- 899 ADMINISTRATIVE PROCEDURES ACT / REVIEW OR APPEAL OF AGENCY DECISION

OTHER STATUTES - "8" MONTHS DISCOVERY TRACK

- 410 ANTITRUST
- 850 SECURITIES / COMMODITIES / EXCHANGE

OTHER STATUTES - "0" MONTHS DISCOVERY TRACK

- 896 ARBITRATION (Confirm / Vacate / Order / Modify)

*** PLEASE NOTE DISCOVERY TRACK FOR EACH CASE TYPE. SEE LOCAL RULE 26.3**

VII. REQUESTED IN COMPLAINT:

CHECK IF CLASS ACTION UNDER F.R.Civ.P. 23 DEMAND \$ _____

JURY DEMAND YES NO (CHECK YES ONLY IF DEMANDED IN COMPLAINT)

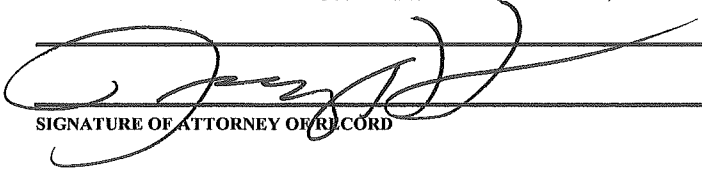
VIII. RELATED/REFILED CASE(S) IF ANY

JUDGE _____ DOCKET NO. _____

CIVIL CASES ARE DEEMED RELATED IF THE PENDING CASE INVOLVES: (CHECK APPROPRIATE BOX)

- 1. PROPERTY INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.
- 2. SAME ISSUE OF FACT OR ARISES OUT OF THE SAME EVENT OR TRANSACTION INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.
- 3. VALIDITY OR INFRINGEMENT OF THE SAME PATENT, COPYRIGHT OR TRADEMARK INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.
- 4. APPEALS ARISING OUT OF THE SAME BANKRUPTCY CASE AND ANY CASE RELATED THERETO WHICH HAVE BEEN DECIDED BY THE SAME BANKRUPTCY JUDGE.
- 5. REPETITIVE CASES FILED BY PRO SE LITIGANTS.
- 6. COMPANION OR RELATED CASE TO CASE(S) BEING SIMULTANEOUSLY FILED (INCLUDE ABBREVIATED STYLE OF OTHER CASE(S)):

- 7. EITHER SAME OR ALL OF THE PARTIES AND ISSUES IN THIS CASE WERE PREVIOUSLY INVOLVED IN CASE NO. _____, WHICH WAS DISMISSED. This case IS IS NOT (check one box) SUBSTANTIALLY THE SAME CASE.



SIGNATURE OF ATTORNEY OF RECORD

November 7, 2013

DATE