UNITED STATES DISRICT 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 offood 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
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UNITED STATES OF AMERICA Plaintiff, 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.	)	CIVIL CASE NO.

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.

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