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**
	)	
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 HC1 (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.

ANSWER AND JURY DEMAND ON BEHALF OF CLAIMANTS HI-TECH PHARMACEUTICALS, INC. AND JARED WHEAT

COME NOW, Claimants Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), and its sole shareholder Jared Wheat ("Wheat") (collectively, "the Claimants"), by and through undersigned counsel, and file this Answer and Jury Demand, as follows:

1. Upon information and belief, the Claimants admit the allegations contained in Paragraph 1 of the Complaint.

2. Upon information and belief, the Claimants admit the allegations contained in Paragraph 2 of the Complaint.

3. Upon information and belief, the Claimants admit the allegations contained in Paragraph 3 of the Complaint.

4. Upon information and belief, the Claimants admit the allegations contained in Paragraph 4 of the Complaint.

5. Upon information and belief, the Claimants admit that the above-listed property contains DMAA or its chemical equivalent and has moved in interstate commerce. The Claimants deny that the articles of food are adulterated and deny that DMAA or its chemical equivalent is unsafe within the meaning of 21 U.S.C. § 348.

6. The Claimants deny that they hold the above-listed property illegally and deny that the property is liable to seizure, condemnation, and forfeiture pursuant to 21 U.S.C. § 334 and demand strict proof thereof.

7. Upon information and belief, the Claimants admit the allegations contained in Paragraph 7.

8. The Claimants deny the allegations contained in Paragraph 8 and demand strict proof thereof.

9. Upon information and belief, the Claimants admit the allegations contained in Paragraph 9.

10. The Claimants deny the allegations contained in Paragraph 10 and demand strict proof thereof.

11. The Claimants deny the allegations contained in Paragraph 11 and demand strict proof thereof.

12. The Claimants deny the allegations contained in Paragraph 12 and demand strict proof thereof.

13. The Claimants deny the allegations contained in Paragraph 13 and demand strict proof thereof.

AFFIRMATIVE DEFENSES

1. The Complaint fails to state a claim upon which relief can be granted.

2. The conduct of the Plaintiff in bringing this action and in seizing the Defendant Properties amounts to a denial of Claimants' rights to Due Process of Law under the Fifth Amendment to the Constitution of the United States.

3. The conduct of the Plaintiff in bringing this action and in seizing the Defendant Properties constitutes a taking under the Fifth Amendment to the Constitution of the United States and requires that the Plaintiff pay Claimants just compensation for the complete loss of Defendant Properties.

4. Claimants assert the affirmative defense of good faith.

The Government Has Not Shown the Products Are Adulterated

5. None of the Defendant Properties are subject to forfeiture under the laws of the United States. The Government's Complaint ignores the complex statutory scheme that regulates DMAA. Dietary supplements, including those manufactured, produced, marketed, distributed and sold by Hi-

Tech, are regulated pursuant to the Dietary Supplement Health and Education Act ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325 (1994), which amended the Federal Food, Drug and Cosmetic Act ("FFDCA").

6. Under DSHEA, a dietary supplement is deemed "adulterated" if it presents a "significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use." 21 U.S.C. § 342(f)(1)(A).

7. Furthermore, under DSHEA, dietary supplements are regulated as a subset of foods, rather than drugs, unless the supplement producers assert disease claims that bring the supplement within the definition of a drug under the FFDCA. *See* 21 U.S.C. § 321(ff) (defining "dietary supplement"), (g)(1) (defining "drug"); *see also* 21 U.S.C. § 343(r)(6) (identifying claims that may be made by dietary supplement manufacturers and those claims which are prohibited).

8. Because dietary supplements are classified as foods, manufacturers and producers are *not* required to provide evidence of product safety or efficacy before marketing dietary supplement products. Dietary supplements are legally presumed to be safe. In any proceeding under DSHEA, the "United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated." 21 U.S.C. § 342(f)(1). Neither the

Food and Drug Administration ("FDA") nor the United States Attorney's Office has made any attempt to meet that burden.

9. DSHEA covers "dietary ingredients." A dietary ingredient is defined as a "vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any dietary ingredient [from the preceding categories]." 21 U.S.C. § 321(ff)(1) (internal subsection divisions omitted). Dietary ingredients include both naturally occurring and synthetically produced versions of the same ingredient. The FDA has recognized the equivalence of natural and synthetically produced dietary ingredients in the context of several vitamins and other ingredients.

10. The above statutory framework applies generally to dietary ingredients marketed in the United States prior to October 15, 1994. Dietary ingredients introduced into the marketplace after that date, i.e., "new dietary ingredients," require notification to the FDA at least 75 days prior to the marketing of the ingredient with information regarding the ingredient's safety. 21 U.S.C. § 350b(a)(2).

11. The effect of the above requirements is that, typically, the FDA only regulates or prevents the sale of "adulterated" dietary supplements on a

"product-by-product basis" rather than on a "class basis." To date, there has been only a single occasion in which the FDA has taken action against an entire class of dietary supplements through the above referenced procedures. *See Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk*. 69 Fed. Reg. 6788 (February 11, 2004), codified at 21 C.F.R. § 119.1. The FDA has *not* followed this procedure regarding dietary supplements that contain DMAA.

12. DMAA is a natural constituent of the geranium plant, *Pelargonium graveolens.* Geraniums (which contain DMAA) have been marketed in the United States since before October 15, 1994. The plant's leaves are used in salads and its oil as a flavoring. No fewer than four published, peer-reviewed scientific studies have confirmed the presence of DMAA in the geranium plant. Large, established, and reputable laboratories, such as Cantox Health Sciences International, have confirmed the presence of DMAA in the geranium plant.

13. DMAA has been the subject of at least a dozen peer-reviewed scientific studies, making it one of the most studied botanical products in the United States. Two of these studies, commissioned and paid for by Hi-Tech, were of Hi-Tech products that contained DMAA. The Government is attempting to forfeit one of those products. None of the scientific studies regarding DMAA has raised any issue regarding its safety. Consumers have

used products containing DMAA millions of times virtually without incident.

CONCLUSION

The Government's forfeiture action is without basis in law and should be dismissed. If the case is not dismissed, Claimants demand a jury trial in this action.

Respectfully submitted this 7th day of January, 2014.

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CERTIFICATION PURSUANT TO LOCAL RULE 7.1(D)

Pursuant to Local Rules 5.1(C) and 7.1(D), I hereby certify that the above document was prepared in Microsoft Word using 14-point Times New Roman font.

CERTIFICATE OF SERVICE

I hereby certify that the above document was electronically filed using the CM/ECF system and was served upon counsel of record via electronic mail on this the 7th day of January, 2014.

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