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

UNITED STATES OF AMERICA, Plaintiff, v. Undetermined quantities of all articles of finished and in-process foods, etc. Defendants, and HI-TECH PHARMACEUTICALS, INC. and JARED WHEAT, Claimants.	Civil Action No. 1:13-cv-3675 Hon. Willis B. Hunt, Jr.
HI-TECH PHARMACEUTICALS, INC., Plaintiff, v. MARGARET A. HAMBURG, M.D., *et al*. Defendants.	

CLAIMANTS HI-TECH PHARMACEUTICALS, INC., AND JARED WHEAT'S MOTION TO STAY PENDING RECONSIDERATION AND APPEAL

I. INTRODUCTION

Since the inception of this litigation, substantial quantities of Hi-Tech Pharmaceutical Inc.'s ("Hi Tech," or, together with Jared Wheat, "Claimants") goods remain impounded at Hi-Tech's facilities in Georgia, unsold and unused. Claimants' Motion for Summary Judgment ("MSJ") Wenik Decl.[1] (Doc. No. 108-3), Ex. 3, United States' Responses to Requests for Admission at Requests 12 and 13 (Doc. No. 108-4). Much of the product in question is finished goods sold under various brand names such as Fastin, Stimerex-ES, Yellow Scorpion, and other names. Other items consist of raw materials/ingredients used by Hi-Tech to produce dietary supplements. The common theme is that the impounded goods contain DMAA.

On April 3, 2017, the Court granted summary judgment on all claims in favor of the Government and denied Claimants' motion for summary judgment. Doc. No. 140 ("April 3 Order"); Doc 141 ("April 3 Judgment"). Although the Court adopted Claimants' position that DMAA is present in geraniums, and refuted the Government's many weak arguments to the contrary, it surprisingly held that

[1] All citations to the MSJ Wenik Decl. refer to the declaration of Jack Wenik, Esq., submitted in support of Claimants' Motion for Summary Judgment, Doc. 108-3, and the exhibits thereto, Docs. 108-4 to 108-8.

DMAA should not be considered a dietary ingredient under the Dietary Supplement Health and Education Act of 1994 ("DSHEA") because there was purportedly no evidence in the record that DMAA could be extracted from geraniums in "usable quantities." April 3 Order at 9. Thus, the Court ordered that the products at issue be condemned and forfeited to the United States for destruction and judgment was entered.

As demonstrated below, Claimants have satisfied the requirements for a stay pending their motion for reconsideration and, if necessary, appeal of the order and judgment. Indeed, it is likely that Claimants will prevail on their motion for reconsideration or upon appellate review because the Court's opinion failed to provide any reference to a statute, legislative history, or case law to support the novel and unbriefed position set forth in the April 3 Order. Furthermore, absent a stay, Claimants are certain to face irreparable harm as Claimants' goods will be destroyed. A stay will neither injure the Government nor harm the public interest because the *status quo* will be preserved while the novel legal reasoning at the heart of the April 3 Order is further vetted and reviewed. LR 7.2(E); Fed. R. Civ. P. 62(b); Fed. R. App. P. 8(a). Therefore, Claimants respectfully request that the Court stay the order pending reconsideration and, if necessary, appellate review.

II. STATEMENT OF FACTS

Hi-Tech is a Georgia corporation with its principal place of business in Georgia. Hi-Tech is one of the largest manufacturers and distributors of dietary supplements, including weight loss products, in the United States. Hi-Tech sells its products through more than 100,000 retail locations including, for example, GNC, CVS, Wal-Mart, K-Mart, Kroger, and convenience stores nationwide. Hi-Tech also sells directly to consumers, healthcare practitioners, and food and dietary supplement companies. Doc. No. 41-1, ¶ 5. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 66, Claimants' Administrative Procedure Act ("APA") Complaint; Answer of United States, Doc. No. 52, ¶ 5.

As this Court has acknowledged, Hi-Tech incorporates DMAA into many of the dietary supplements it manufactures and sells including, for example, Black Widow, Lipodrene, Yellow Scorpion, Fastin XR, and Stimerex-ES. Doc. No. 140 at 1. Since 2010, Hi-Tech has sold over 200 million doses of DMAA containing products with only a handful of adverse events of any sort. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 2, Declaration of Michael Lumpkin, Ph.D., DABT ("Lumpkin Decl.") at ¶¶ 98-99.

A. The FDA's Campaign to Ban DMAA

As detailed in Claimants' summary judgment motion, Doc. 108, after Amy Eichner of the United States Anti-Doping Agency ("USADA") undertook a campaign to ban DMAA, in April 2012, the U.S. Food and Drug Administration ("FDA") sent Warning Letters to several companies that marketed DMAA-containing products, advising them that DMAA was dangerous and not a dietary ingredient under DSHEA. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 19, April 27, 2012 Press Release. Hi-Tech was not one of the companies to receive such a letter.

Subsequently, the FDA trumpeted its success by noting that all but one of the companies that had received a warning letter had removed DMAA from their products and the marketplace. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 20, FDA Consumer Alert entitled "Stimulant Potentially Dangerous to Health, FDA Warns," which was Exhibit 28 to the Deposition of Daniel Fabricant, Ph.D. ("Dr. Fabricant"), at 2. The one holdout, USP Labs, LLC ("UPS Labs"), ultimately caved to FDA pressure in April 2013 and removed DMAA from its products. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 21, (April 2013 email correspondence among Dr. Daniel Fabricant, Mahmoud ElSohly, Ph.D. ("Dr. ElSohly") and Dr. Ikhlas A. Khan, Ph.D. ("Dr. Khan") containing the USP Labs press release). In

fact, in July of 2013, under continuing FDA pressure, USP Labs "voluntarily" destroyed $8 million worth of DMAA containing products. Doc. 41-1, ¶ 21.

B. The FDA Turns Its Intimidation Campaign Against Hi-Tech

In early November 2013, the *Atlanta Journal Constitution* published a lengthy article that discussed Claimants' sale of products containing DMAA. Wenik Decl. (Doc. No. 108-3), Ex. 28, November 2, 2013 *Atlanta Journal Constitution* article. In the article, reporter Danny Robbins related comments by the FDA's Dr. Fabricant that the FDA was not aware that Claimants were marketing DMAA-containing products until being informed about this by the *Atlanta Journal Constitution*. *Id.*

Following an inspection of Hi-Tech's facilities in Norcross, Georgia, in November 2013, the FDA issued an Administrative Detention Order against inventories of dietary supplement products containing DMAA, with an approximate value of $2.2 million. Doc. No. 41-1, ¶ 22; Doc. No. 41-7 (Ex. 1).

Hi-Tech filed a Notice of Intent to request a hearing and to appeal and timely filed an administrative appeal from the FDA's Detention Order. Doc. No. 41-8 (FDA Br., Ex. 2); Doc. Nos. 41-9, 41-10 (FDA Br. Ex. 6). Before it filed its administrative appeal, Hi-Tech also filed its action in the District of Columbia District Court under the Administrative Procedure Act ("APA") seeking

declaratory and injunctive relief to require the FDA to comply with its legal obligations under DSHEA and to refrain from taking arbitrary and capricious actions against Hi-Tech and its DMAA-containing products.

C. The FDA Responded to Hi-Tech by Terminating Its Detention Order and Filing Its *In Rem* Seizure Complaint

After Hi-Tech filed its APA claims, and after Hi-Tech gave notice of its intent to appeal the FDA's Detention Order, the FDA filed its *in rem* seizure complaint in the Northern District of Georgia and issued a warrant of arrest for the products covered by its Detention Order. Doc.1. Additionally, after the FDA received Hi-Tech's administrative appeal, it terminated the Detention Order. Doc. Nos. 41-8, 41-9, 41-10. Thereafter, Claimants filed a verified claim and an answer in response to the seizure complaint. Doc. Nos. 11, 14. An Amended Complaint and an Amended Answer were subsequently filed. Doc. Nos. 25, 26.

In July 2014, the District of Columbia District Court transferred the APA claims to this Court. On August 1, 2014, the Court merged Hi-Tech's APA action with the FDA's seizure action and dismissed the separately docketed case created by the transfer of the APA action. Doc. No. 29. On August 28, 2014, this Court clarified that its August 1, 2014 Order was procedural only; Hi-Tech's claims against the FDA were not affected by the administrative dismissal of the other case. Doc. No. 33.

D. Motions for Summary Judgment

On December 30, 2016, both Claimants and the Government moved for summary judgment. Doc. Nos. 107, 108. On April 3, 2017, the Court granted the Government's Motion for Summary Judgment, and denied Claimants' Motion for Summary Judgment. April 3 Judgment. The court held that "judgment [was] entered as to all claims in favor of the Government and against the Defendants unde[te]rmined 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 and also against Claimants . . . as to the forfeiture action, and to all claims in the suit originally filed in the District Court for the District of Columbia as 1:13-CV-1747, later transferred to this Court as 1:14-CV-2479 and later merged into this action." April 3 Judgment.

In the interest of fairness, as set forth below, the instant motion to stay pending reconsideration and/or appeal is filed to preserve the status quo and prevent destruction of Claimants' goods pending further review.

III. LEGAL STANDARD

The standards for granting a stay pending reconsideration or appeal are well settled in this Circuit. A stay pending reconsideration or appeal should be granted where the movant shows that: (1) it is likely to prevail on the merits of its appeal;

(2) the movant will sustain irreparable injury absent such relief; (3) issuing a stay would not harm the public interest; and (4) issuing a stay would not harm the opposing party. *See Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *Venus Lines Agency v. Cvg Industria Venezolana De Aluminio*, C.A., 210 F.3d 1309, 1313 (11th Cir. 2000); *see also* LR 7.2(E); Fed. R. Civ. P. 62(b); Fed. R. App. P. 8(a). "[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes in its docket with economy of time and effort for itself, for counsel and for litigants." *Landis v. N. Am. Co*., 299 U.S. 248, 254-55 (1936).

Where the balance of the equities weighs heavily in favor of granting the stay, the movant need only present a substantial case on the merits involving a serious legal question. *See United States v. Hamilton*, 963 F.2d 322, 323 (11th Cir. 1992); *Ruiz v. Estelle*, 650 F.2d 555, 565 (5th Cir. 1981). Granting a stay "maintaining the *status quo* pending appeal 'is appropriate when a serious legal question is presented, when little if any harm will befall other interested persons or the public and when denial of the [stay] would inflict irreparable injury on the movant.'" *LabMD, Inc. v. FTC*, 2016 U.S. App. LEXIS 23559, *6-7 (11th Cir. Nov. 10, 2016) (quoting *Ruiz*, 650 F.2d at 565). "Judicial protection" is warranted "where relative harm and the uncertainty of final disposition justify" a stay. *Ruiz*,

650 F.2d at 565. As set forth below, a stay pending reconsideration and/or appeal is plainly warranted under these standards.

IV. ARGUMENT

A. The Court Should Stay its April 3 Order Pending Resolution of this Motion for Reconsideration, or, Alternatively, Pending Appeal of that Order.

i. Hi-Tech will likely prevail on the merits of its motion for reconsideration and, if such motion fails, on appellate review

The court is "not required to find that ultimate success by the movant is a mathematical probability" when balancing the equities of a stay of judgment. *Ruiz*, 650 F.2d at 565, and "indeed, may grant a stay even though its own approach may be contrary to movant's view of the merits," *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc*., 559 F.2d 841, 843 (D.C. Cir. 1977). The "likelihood of success is shown when the [movant] has raised 'questions going to the merits so serious, substantial, difficult and doubtful as to make them a fair ground for litigation and thus for more deliberate inquiry.'" *United States ex rel. Citizen Band Potawatomi Indian Tribe v. Enterprise Management Consultants, Inc.*, 883 F.2d 886, 889 (10th Cir. 1989).

Here, Claimants have made a substantial case on the merits of their motion for reconsideration. Indeed, a stay is appropriate where a court has ruled on "an

admittedly difficult legal question and when the equities of the case suggest that the *status quo* should be maintained." *Holiday Tours, Inc*., 559 F.2d at 844-45. As set forth below, the Court's interpretation of DSHEA in its April 3 Order was, respectfully, clearly erroneous from both a legal and factual perspective. As a result, the Court clearly erred in ruling that the Claimants' DMAA and DMAA-containing products do not qualify as dietary ingredients pursuant to 21 U.S.C. § 321(ff) and should therefore be condemned and destroyed. Thus, Claimants will likely be successful on appeal.

a. The Court's *Sua Sponte* Determination That DMAA Must Be Extractable In "Usable Quantities" Is A Novel Interpretation Not Argued By The Parties and Not Supported By Law

In the April 3 Order, the Court correctly acknowledged that "the Government ha[d] failed to meet its burden of establishing that DMAA ha[d] not been found in geraniums." April 3 Order at 7. That holding was based on the fact that DMAA has "been found in a species of a geranium plant," as proven by "three published papers that provided the details of tests detecting DMAA." *Id*. at 5. The Court took judicial notice of a paper surveying DMAA studies, 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), and noted that the author concluded: (1) "[o]verall, these studies show that 1,3-DMAA

is found naturally in some, but not all, geranium plants and extracted geranium oils;" and (2) "the studies that failed to find DMAA used extraction techniques that may not have been suitable for retention of DMAA due to its volatility." *Id*.

Furthermore, the Court rejected the Government's three main critiques of scientific papers failing to detect DMAA, explaining: (1) the papers cited by the Government that did not detect DMAA "may not have been suitable for [detection] of DMAA due to its volatility;" (2) Dr. Paula Brown's testimony regarding the ability of geraniums to produce DMAA was not "unequivocal" and did not provide anything "close to uncontroverted evidence that geraniums cannot make DMAA;" and (3) the Government's claims that DMAA detected in geraniums was the result of contamination "fail[ed] to address the fact that other studies did find DMAA." *Id*. at 5-6. As such, the Court was "unswayed by the Government's argument that it is impossible for the geranium in question to synthesize DMAA," and concluded that "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. . . this Court would be inclined to find that the Government has failed to meet its burden of establishing that DMAA has been found in geraniums." *Id*. at 6-7. With due respect to the Court, because this was the dispositive issue in this case, that should

have been the end of the Court's analysis and summary judgment should have been entered in favor of Claimants.

The Court's ensuing analysis, however, suffers from a key legal error. Absent any briefing whatsoever from either Claimants or the Government, the Court concluded 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 . . . ." *Id.* at 9 (emphasis added). The Court failed to reference DSHEA,[2] its legislative history, or case law to support this novel position. Moreover, this interpretation ignores the fact that Congress clearly could have, but did not, include a requirement that a substance

---

[2] DSHEA defines the following substances as a dietary ingredient:

> (A) a vitamin;
>
> (B) a mineral;
>
> (C) an herb or other botanical;
>
> (D) an amino acid;
>
> (E) 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) (emphasis added).

qualifies as "a concentrate, metabolite, constituent, extract, or combination" of a dietary ingredient only if it can be extracted in "usable quantities." By engrafting this "usable quantity" requirement onto 21 U.S.C. § 321(ff)(1), the Court has impermissibly encroached on the policy making prerogative of Congress. Simply put, there is no requirement set forth anywhere that any such extract or constituent be present in anything above "trace" quantities.

Notably, the Government in its briefing did not even advocate the position reached by the Court. *See* Gov't Motion for Summary Judgment, Doc. No. 107-1 at 1 ("The issue in this case is whether [DMAA] is a 'dietary ingredient' . . . . To decide this issue, this Court needs to resolve [whether] DMAA is naturally produced by geranium plants[.]"). The Government—similar to Claimants—took the position that the presence of DMAA in geraniums, even in trace amounts, would render it a dietary ingredient under DSHEA. Answer of the United States, Doc. No. 52, ¶ 14; *see also* MSJ Wenik Decl. (Doc. 108-3), Ex. 35, Welch Dep. at 27:7-27:23 (noting that the Government's regulatory expert, Dr. Cara Welch, testified that synthetic ingredients can be dietary ingredients under DSHEA). Moreover, the Court accepted the parties' position that synthetically produced DMAA could qualify as a botanical under DSHEA. *See* April 3 Order at 8.

While focusing on placing DMAA into the "botanical" category set out in DSHEA, the Court ignored the definition set forth in DSHEA most relevant to this litigation —"constituent." Congress explicitly included "constituents" of botanicals as dietary ingredients under DSHEA and **did not** set any quantitative limit as to what qualifies as such. 21 U.S.C. § 321(ff)(1)(F). As a constituent, DMAA qualifies as a dietary ingredient, even if it is only present at "trace" levels in geraniums. The Court's reading of DSHEA simply reads the word "constituent" out of the statute in order to further the Court's opinion about what it thinks Congress conceivably or "inconceivabl[y]" meant when it drafted DSHEA. April 3 Order at 8. The Court may consider its interpretation the wiser one from a policy perspective—but that is not its role here. *See Badaracco v. Commissioner*, 464 U.S. 386, 398 (1984) ("Courts are not authorized to rewrite a statute because they might deem its effects susceptible of improvements."); *Blount v. Rizzi*, 400 U.S. 410, 419 (1971) ("It is for Congress, not this Court, to rewrite the statute."); *Korman v. HBC Florida, Inc.*, 182 F.3d 1291, 1296 (11th Cir.1999) ("It is not the business of courts to rewrite statutes."). As the Court is well aware, "[w]here the intent of Congress is expressed in the text of a statute in reasonably plain terms, [it] must give effect to that intent. *Chater*, 81 F.3d at 1081 (citing *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 570 (1982)). Here, the intent of Congress was

clear: constituents of a botanical can qualify as a dietary ingredient under DSHEA. To this point, even the Government agrees. *See* Gov't Motion for Summary Judgment, Doc. No. 107-1, at 1 (explaining that the key legal and factual issue in this case revolved around whether DMAA is present in geraniums). As a result, the Court's interpretation of DSHEA otherwise constitutes clear error that requires reconsideration.

Lastly, aside from DMAA, there are numerous other constituents of organic substances that naturally occur in minute quantities which are made synthetically for dietary supplements. For example, both Resveratrol, an ingredient in grapes (and in wine) and CoQ10, which is an antioxidant that is synthesized in the body and is found in foods such as beef, chicken, fish, peanuts, and strawberries, can be commercially synthesized and are routinely included in dietary supplements. Both of these substances have long been recognized as dietary ingredients under DSHEA. Yet, Resveratrol is found only in very small amounts in red wines, which have a Resveratrol content (per 5-oz glass) of 0.03-1.07 mg. *See* Oregon State University, Linus Pauling Institute Micronutrient Information Center – Resveratrol Entry, available at http://lpi.oregonstate.edu/mic/dietary-factors/phytochemicals/resveratrol. Indeed, the levels of Resveratrol found in food vary considerably, even

in the same food from season to season and batch to batch.[3] As the Court explained, DMAA has been found as high as 13 parts per million (ppm), which is approximately the same as the highest amount of Resveratrol found in red wine at 14.3 ppm or mg/L. *See* April 3 Order at 7. So long as DMAA is found in a botanical, as a constituent of geraniums, its synthetic sourcing for Hi-Tech's dietary supplements has no bearing on whether or not it is a dietary ingredient under DSHEA.

---

[3] The following table sets out the average *trans*-Resveratrol content of red wines:

Variety	**Lowest (mg/L)**	**Highest (mg/L)**	**Mean (mg/L)**	**5-oz Glass (mg)**
Pinot Noir	0.2	11.9	3.6 ± 2.9	0.5
Merlot	0.3	14.3	2.8 ± 2.6	0.4
Zweigelt	0.6	4.7	1.9 ± 1.2	0.3
Shiraz	0.2	3.2	1.8 ± 0.9	0.3
Cabernet Sauvignon	-	9.3	1.7 ± 1.7	0.2
Red wines (global)	-	14.3	1.9 ± 1.7	0.3

See id. (noting that Resveratrol is produced in certain plants in response to stress, injury, fungal infection, or ultraviolet radiation).

b. The Court Incorrectly Concluded that Claimants Lack Evidence that DMAA Cannot be Extracted from Geraniums in a Commercially Usable Quantity

Reconsideration is appropriate for another reason. The Court found that "while studies might have found the presence of DMAA in geraniums, no one has ever extracted DMAA for any commercial, medicinal or other purpose. It merely has been detected." April 3 Order at 7.

Assuming, *arguendo*, that the Court is correct that, in order to qualify as a dietary ingredient under DSHEA, April 3 Order at 9, a constituent of a botanical must be extractable in a "usable quantity," there is no evidence in the record before this Court that DMAA cannot be extracted from geraniums in a usable amount. Rather, one of Claimants' experts, Dr. Marvin Heuer, whose declaration was submitted in support of Claimants' Motion for Summary Judgment and whose deposition transcript is also part of the record, Doc. No. 130, noted that patent applications were filed to commercially extract of DMAA from geraniums. MSJ Wenik Decl. (Doc. No. 108-3), Ex. 38, Heuer Decl., ¶58. Dr. Heuer was questioned about these specific patents at his deposition by the Government. Heuer Dep. Tr. (Doc. No. 130) at 225:21-232:12 and exhibits 7 and 8 thereto (U.S. Patent Applications 2012/0225144 and 2012/0225142). These patent applications describe an extraction method that optimizes the DMAA content of the oil by

extracting the oil with an alcohol/water mixture, separating geranium oil and water phases, concentrating and drying the aqueous phase to a powder, and then, after purifying the oil, combing the powder with the purified oil, achieving a 1% to 3% DMAA concentration. *See id*. (Heuer Dep. Exs. 7 and 8). These patents, and Dr. Heuer's testimony regarding them, are evidence which surely creates a disputed issue of fact regarding the ability to extract DMAA from geraniums in "usable quantities."

Thus, there was no basis for an entry of summary judgment in favor of the Government on this disputed set of facts. *See Espanola Way Corp. v. Meyerson*, 690 F.2d 827, 830 (11th Cir. 1982) (denying summary judgment based on "meager facts [that were] too equivocal to warrant summary judgment"); *Sprint Communs. Co. L.P. v. Vonage Holdings Corp.*, 500 F. Supp. 2d 1290, 1341 (D. Kan. 2007) (denying summary judgment on issue where movant bore the "burden of proof" and that was solely supported by an "equivocal and qualified statement" that lacked any other "affirmative evidence"); *Council for Hearing Impaired Long Island, Inc. v. Ambach*, 610 F. Supp. 1051, 1058 (E.D.N.Y. 1985) ("Where questions of material fact are not resolved by a stipulation, or the stipulation is equivocal, summary judgment must be denied.").

c. It Is Impermissible For The Court To Enter Summary Judgment Without Notice to The Parties of The Dispositive Issue.

Finally, entry of summary judgment against Claimants on the basis that DMAA cannot be extracted in "usable quantities" was inappropriate because Claimants were never put on notice that such evidence would be dispositive. Until the Court issued its April 3 Order, the ability to extract DMAA from geraniums in a "usable quantity" was not in dispute amongst the parties. Indeed, in the hundreds of pages of briefing in support of the cross-motions for summary judgment, not a single page addresses this very issue that the Court found was central to its ruling. As such, Claimants surely were unaware that the Court would consider this issue dispositive in its analysis. *See Artistic Entm't, Inc. v. City of Warner Robins*, 331 F.3d 1196, 1201 (11th Cir. 2003) (*sua sponte* summary judgment decision appropriate only where "(1) purely legal issues are involved or (2) the evidentiary record is complete and the parties have been given the opportunity to respond."); *Montgomery v. City of Ames*, 749 F.3d 689, 697 (8th Cir. 2014) ("A district court commits reversible error by granting summary judgment on an issue not raised or discussed by the parties if the losing party did not have notice and an opportunity to respond"); *Acumed LLC v. Advanced Surgical Servs.*, 561 F.3d 199, 223–24 (3d Cir. 2009) (A court "must provide the parties with notice of its intention to

consider granting summary judgment so that they have an opportunity to marshal evidence on the motion for submission to the court."); *Simpson v. Merchants. Recovery Bureau, Inc.*, 171 F.3d 546, 549 (7th Cir. 1999) ("While not encouraged, a district court can enter summary judgment *sua sponte*, or on its own motion, under certain limited circumstances … [However,] granting summary judgment *sua sponte* warrants special caution" and generally requires that the party against whom summary judgment is entered have notice and an opportunity to present its evidence.); 11-56 Moore's Federal Practice - Civil § 56.71 ("A court may not grant summary judgment for a nonmovant, grant summary judgment on a ground not specified in a motion, or grant summary judgment *sua sponte* until the court provides the parties "notice" of its intention to do so and grants the parties "a reasonable time" to respond to the proposed summary judgment before acting."). As such, Claimants must prevail—whether by reconsideration or upon appellate review—in their request to vacate the April 3 Order to permit Claimants to present evidence that DMAA can be extracted from geraniums in "usable quantities."

ii. Upon Forfeiture of the Seized Products, Hi-Tech Will Suffer Irreparable Harm

Claimants' irreparable harm upon execution of the April 3 Judgment, together with the strong likelihood of Claimants prevailing upon appeal, are the "most critical" factors in this Court's determination to grant a stay of the April 3

Order. *Nken v. Holder*, 556 U.S. 418, 434 (2009) (quotation omitted). As this is an *in rem* proceeding, destruction of the Claimants' products pending reconsideration and/or appellate review—which constitutes "action of a character which cannot be reversed by the court of appeals"—would render the court of appeals "powerless to grant the relief" requested by Claimants and thus frustrate their right to meaningful review. *Am. Grain Asso. v. Lee-Vac, Ltd.*, 630 F.2d 245, 247 (5th Cir. 1980); *see id.* ("Under such circumstances the appeal will be dismissed as moot."); *see also* *In re Kahihikolo*, 807 F.2d 1540, 1542 (11th Cir. 1987) (appeal dismissed as moot because the appellant failed to request a stay of judgment pending appeal and the *real property* at issue was sold by the appellee pre-appeal). A loss of a meaningful right to appellate review constitutes irreparable harm. *See Providence Journal Co. v. FBI*, 595 F.2d 889, 890 (1st Cir. 1979) ("Meaningful review entails having the reviewing court take a fresh look at the decision of the trial court, before it becomes irrevocable. Appellants' right of appeal here will become moot unless the stay is continued pending determination of the appeals.").

Notwithstanding the harm already bestowed upon Hi-Tech due to its products losing potency or expiring during the pendency of the past three years' of seizure, the destruction of Hi-Tech's products would also destroy the remaining product while the ultimate legal questions are still in contention and under review.

Furthermore, this will deprive the parties of any ability to either forensically test or physically examine the products if the dispute requires such following a decision on Claimants' motion for reconsideration or eventual appeal.

These harms—loss of appellate review and destruction of key evidence—are irreparable and precisely the type of harm that should be prevented by a stay. These injuries cannot be rectified once this Court permits the goods to be destroyed by the Government—there can be no restitution by the Government, no method of making Claimants whole. The destruction of Hi-Tech's products constitutes irreparable harm because it is irreversible and permanent and would make any return to the *status quo* impossible. This simply fact alone warrants issuance of a stay.

iii. The United States Will Not Be Harmed By A Stay Pending Resolution Of This Motion For Reconsideration And, If Appropriate, Appellate Review

The Government will suffer no cognizable injury if condemnation of Hi-Tech's products is stayed pending reconsideration or appellate review. Even assuming ultimate victory by the Government in this matter, any right to condemn the products can be fully vindicated after a final decision on reconsideration and, if applicable, on appellate review. There is no financial cost to the Government in staying the condemnation and destruction of the seized products; the products are

maintained in Hi-Tech's facilities at solely Claimants' cost. Indeed, the only harm a stay could potentially cause to the Government is a relatively brief, additional delay in condemnation of products that are already subject to the November 2013 seizure. Moreover, no one will be harmed by the grant of a stay. The Government will be in no worse position, and, at most, the Government will simply have to wait a little longer to destroy the goods at issue.

iv. The Public Interest Is Unaffected By The Grant Of A Stay.

Finally, the public interests protected by DSHEA will be unaffected if a stay is granted pending reconsideration or appellate review. The relevant interest under DSHEA is to provide consumers access to, and accurate information about, dietary supplements. Pub. L. 103-417, 108 Stat. 4325 (1994); *see also All. for Nat. Health US v. Sebelius*, 775 F. Supp. 2d 114, 129 (D.D.C. 2011). The requested stay would simply act to maintain the *status quo*—the products at issue are already seized and under the control of the FDA. The very nature of this *in rem* action—that Hi-Tech's products are seized and in the control of the Government—consequently means that the continued existence of the products has no effect on the public interest pending resolution of Claimants' motion. By any stretch of the imagination, "little if any harm" will befall the public as a result of this stay pending appellate review. *Ruiz*, 650 F.2d at 565.

B. The Seized Products Serve as a Bond Protecting the Government's Interest in this Litigation

In general, pending the resolution of a motion for reconsideration under Federal Rule of Civil Procedure 60, the party requesting a stay posts bond or security sufficient to protect the other party's interests in the outcome of the litigation. *Poplar Grove Planting and Refining Co., Inc. v. Bache Halsey Stuart, Inc.*, 600 F.2d 1189 (5th Cir. 1979); *see also* Fed. R. Civ. P. 62(d). Here, the Government is already in control of Hi-Tech's seized products. Valued at approximately two million dollars, the seized products are equivalent to a full monetary bond. The Government has presented no evidence during this litigation to even suggest that Claimants would not respond to this Court's April 3 Order and Judgment rendered if it becomes final, and is at no risk of losing its interest in this case—the seized products—by the entry of a stay. Accordingly, if the Court in its discretion determines that security is necessary to enter the stay, the millions of dollars' worth of products in the Government's control are sufficient to protect the Government's ongoing interest and should be deemed to be the full amount of security required.

V. CONCLUSION

For each of the foregoing reasons, Claimants respectfully request that the Court grant their motion for stay pending resolution of its motion for reconsideration and/or appeal.

Respectfully submitted,

/s/ Jack Wenik
Jack Wenik, Esq.
Epstein Becker & Green, P.C.
One Gateway Center, 13th Floor
Newark, New Jersey 07102
(973) 639-5221
jwenik@ebglaw.com
Admitted Pro Hac Vice

/s/ E. Vaughn Dunnigan
E. Vaughn Dunnigan, Esq.
E. Vaughn Dunnigan, P.C.
2897 N. Druid Hills Rd., Suite 142
Atlanta, Georgia 30329
(404) 663-4291
evdunnigan@hotmail.com
Georgia Bar No. 234350

/s/ Arthur Leach
Arthur Leach, Esq.
Law Offices of Arthur Leach
5780 Windward Parkway, Suite 225
Alpharetta, Georgia 30005
(404) 786-6443
art@arthurleach.com
Georgia Bar No. 442025

/s/ Bruce S. Harvey
Bruce S. Harvey
Law Office of Bruce Harvey
146 Nassau Street, NW
Atlanta, GA 30303
404-659-4628
Email: bruce@bharveylawfirm.com
Georgia Bar No. 335175

Attorneys for Hi-Tech Pharmaceuticals, Inc. and Jared Wheat

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 17th day of April, 2017.

/s/ Jack Wenik

Jack Wenik, Esq.
Epstein Becker & Green, P.C.
One Gateway Center, 13th Floor
Newark, New Jersey 07102
(973) 639-5221
jwenik@ebglaw.com
Admitted Pro Hac Vice

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

UNITED STATES OF AMERICA,

Plaintiff,

v.

Undetermined quantities of all articles of finished and in-process foods, etc.

Defendants,

and

HI-TECH PHARMACEUTICALS, INC. and JARED WHEAT,

Claimants.

HI-TECH PHARMACEUTICALS, INC.,

Plaintiff,

v.
MARGARET A. HAMBURG, M.D., et al.

Defendants.

Civil Action No. 1:13-cv-3675

Hon. Willis B. Hunt, Jr.

[PROPOSED]

ORDER GRANTING HI-TECH PHARMACEUTICALS, INC., AND JARED WHEAT'S MOTION TO STAY PENDING MOTION FOR RECONSIDERATION AND/OR APPEAL

Having read and considered Hi-Tech Pharmaceuticals, Inc. and Jared Wheat's (collectively "Claimants") Motion to Stay Pending Reconsideration and/or Appeal, and the Court having reviewed the submissions and arguments of the parties, and for other good cause shown:

IT IS, on this _____ day of _____, 2017, **ORDERED** that:

1) Claimants' Motion to Stay Pending Reconsideration and/or Appeal is **GRANTED**;

2) The Order and Judgment entered on April 3, 2017 (Docs. 140, 141) are hereby **STAYED** pending disposition of Claimants' Motion for Reconsideration;

3) If Claimants' Motion for Reconsideration is denied, the Order and Judgment Order entered on April 3, 2017 (Docs. 140, 141) are hereby **STAYED** pending Claimants' appeal of the Order and Judgment Order entered on April 3, 2017 (Docs. 140, 141); and

4) Given that approximately $2million of Claimants' goods are already in control of the Government, Claimants shall not be required to post any bond during the pendency of their Motion for Reconsideration or any subsequent appeal, if necessary.

_____
WILLIS B. HUNT, JR.
United States District Judge

Submitted by:
Jack Wenik