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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

United States of America, Plaintiff, vs. Global Vitality, Inc., dba Enzyme Process International, a corporation; Steven D.	**COMPLAINT** Civil No. _____

Roderick; Gorica Blagojevic; individuals,

Defendants.

COMPLAINT

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin Global Vitality, Inc., dba Enzyme Process International ("Global Vitality"), a corporation, and Steven D. Roderick and Gorica Blagojevic, individuals (collectively, "Defendants") from:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343;

B. Violating 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343;

C. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352;

D. Violating 21 U.S.C. § 331(k) by causing articles of drug that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352; and

E. Violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate

commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval under the Act.

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

Defendants

4. Defendant Global Vitality, Inc., dba Enzyme Process International, is incorporated under the laws of the state of Arizona. Global Vitality promotes itself as a dietary supplement manufacturer, contract manufacturer, and private labeler. Global Vitality does business at 470 N. 56th Street, Chandler, Arizona (the "Facility"), within the jurisdiction of this court.

5. Steven D. Roderick is the owner of Global Vitality and the most responsible person at the company. He has ultimate authority over all of the firms' operations, including product formulation, manufacturing, labeling, and sales. He employs a total of approximately twenty-three employees. He also owns and controls the website on which Defendants' products are sold, http://enzymeprocess.co/. Defendant Roderick performs his duties at the Facility.

6. Gorica Blagojevic has been Global Vitality's corporate Secretary since 2019, prior to which she served as the company's manufacturing manager for ten years. She is involved in the manufacturing of dietary supplements, including oversight of the blending, bottling, and testing processes, and performs her duties at the Facility.

7. Defendants have been and are now engaged in the business of manufacturing and distributing:

A. Dietary supplements within the meaning of the Act, which defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet" that contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a 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 of them, and that "is labeled as a dietary supplement" and "is not represented for use as a conventional food or as a sole item of a meal or the diet." 21 U.S.C. § 321(ff). Except for purposes of 21 U.S.C. §§ 321(g) (defining drugs under the Act) and 350f (covering reporting requirements for "reportable food" that will cause serious adverse health consequences to consumers), dietary supplements are deemed to be food under the Act. 21 U.S.C. § 321(ff); and

B. Products that meet the definition of drug under the Act, 21 U.S.C. § 321(g)(1), because Defendants' claims establish that the products are intended to cure, mitigate, treat, or prevent disease and/or affect the structure or function of the body.

8. Defendants receive raw materials that they use to manufacture their products from outside the state of Arizona, including New Jersey and California. Defendants distribute their products to customers throughout the United States, including Connecticut, Illinois, and California.

Defendants' Violations of the Act

Adulterated Dietary Supplements

9. The Act deems a dietary supplement to be adulterated if it is not prepared, packed, and held in conformance with regulations for current good manufacturing practice for dietary supplements ("Dietary Supplement CGMP"). 21 U.S.C. § 342(g)(1). The Dietary Supplement CGMP regulations, set forth at 21 C.F.R. Part 111, are designed to ensure the quality of dietary supplements. These regulations apply to any person who manufactures, packages, labels, or (subject to an exception not relevant here) holds dietary supplements.

10. FDA investigators inspected Defendants' Facility between June and July 2021 (the "2021 inspection"). The 2021 inspection established that the dietary supplements Defendants distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they are prepared, packed, or held in a manner that does not conform to Dietary Supplement CGMP regulations. FDA investigators documented significant deviations from Dietary Supplement CGMP regulations, including but not limited to:

A. Failure to establish component specifications that are necessary to ensure the purity, strength, and composition of dietary supplements manufactured using the components, as required by 21 C.F.R. § 111.70(b)(2);

B. Failure of quality control personnel to ensure that all specifications necessary to support the quality of the finished dietary supplement are met, as required by 21 C.F.R. §§ 111.105(h) and 111.70(a), including Defendants' failure to ensure that specifications for their finished products are met, resulting in Defendants' distribution of finished products that tested positive for E. Coli;

C. Failure to conduct at least one appropriate test or examination to verify the identity of a dietary ingredient, prior to its use, as required by 21 C.F.R. § 111.75(a)(1)(i);

D. Failure to establish finished product specifications for each dietary supplement manufactured for the identity, purity, strength, and composition of the finished batch of dietary supplements, as required by 21 C.F.R. § 111.70(e);

E. Failure to ensure that the tests and examinations used to determine whether product specifications are met are appropriate and supported by scientifically valid methods, as required in 21 C.F.R. § 111.75(h)(1);

F. Failure to maintain and clean equipment, utensils, and all food-contact surfaces, as required by 21 C.F.R. § 111.27; and

G. Failure of operators to have hygienic practices during operations, as required by 21 C.F.R. § 111.10(b).

11. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, or held under conditions that do not meet Dietary Supplement CGMP regulations, 21 C.F.R. Part 111.

12. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) that Defendants hold for sale after shipment in interstate commerce to

become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

Misbranded Dietary Supplements

13. The Act deems a dietary supplement to be misbranded if its label is false or misleading; fails to bear each ingredient; fails to identify the part of the plant (e.g., root, leaves) from which each botanical dietary ingredient in the product is derived; fails to present the nutrition information in a Supplement Facts panel as required by 21 C.F.R. Part 101; fails to bear the correct serving size and number of servings per container; fails to contain the name of the food source from which a major food allergen is derived (shellfish); and fails to include a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event with the dietary supplement. *See* 21 U.S.C. §§ 343(a)(1); (i)(2); (s)(2)(C); (q)(5)(F); (q)(1)(A); (w); and (y).

14. Several of Defendants' dietary supplements are misbranded within the meaning of the Act, 21 U.S.C. § 343, as follows:

A. Defendants' Enzyme Process brand Shark Cartilage product is misbranded within the meaning of 21 U.S.C. § 343(a)(1), because its label is false and misleading in that it states that the product, "contains…shark cartilage…freeze dried, concentrated and then bottled with no added ingredients." However, the product contains magnesium stearate in addition to shark cartilage. Additionally, Defendants' Bone-C-Dent and Food Research brand Hematic Formula products are misbranded within the meaning of 21 U.S.C. § 343(a)(1) in that the products contain added iron and fail to bear warning statements about the risk of fatal poisoning in children under the age of six, as required under 21 C.F.R. § 101.17(e);

B. Defendants' Enzyme Process brand Pituaplex, Food Research brand Serious Brain Enhancer, Food Research brand Hematic Formula, Food Research brand Pro-Enzymes, Food Research brand Probio-Zyme-YST, Food Research brand Simply Lung, Enzyme Process brand Klamath Blue Green Algae, Enzyme Process brand B-50 Complete with Quartrefolic and Methyl B-12, Enzyme Process brand Colo Norm G,

Enzyme Process brand Digeszyme-V, 60 Capsules, Food Research brand Inflam-Enzymes, Enzyme Process brand Olive Leaf 18% with Enzymes, and Enzyme Process brand Enzimmune products are misbranded within the meaning of 21 U.S.C. § 343(i)(2) in that the products are fabricated from two or more ingredients, and the common or usual name of each ingredient is not declared on the products' labels, as required under 21 C.F.R. § 101.4;

C. Defendants' Enzyme Process brand Adrenucleo, Enzyme Process brand B-50 Complete with Quartrefolic and Methyl B-12, Enzyme Process brand Colo Norm G, Enzyme Process brand Alkaplex Green, Enzyme Process brand Alkazyme 3, Food Research brand Pro-Enzymes, Dr. Dale's Wellness Center brand Whole Body & Immune Pro, Food Research brand Probio-Zyme-YST, and Enzyme Process brand Tranquility products are misbranded within the meaning of 21 U.S.C. § 343(s)(2)(C) because the products' labels fail to identify the part of the plant (e.g., root, leaves) from which each botanical dietary ingredient in the product is derived, as required by 21 C.F.R. § 101.4(h)(1). For example, the labels on Defendants' products identify Nopal (prickly pear cactus) in their Enzyme Process brand Adrenucleo, alfalfa and watercress in their Enzyme Process brand B-50 Complete with Quartrefolic and Methyl B-12, and watercress in their Enzyme Process brand Colo Norm G, among others, but their labels fail to identify the part of the plant used to manufacture these products;

D. Defendants' Enzyme Process brand B12, Enzyme Process brand B-50 Complete with Quartrefolic and Methyl B-12, Food Research brand Serious Brain Enhancer, Food Research brand Hematic Formula, Enzyme Process brand Adrenucleo, Enzyme Process brand Bone-C-Dent, Enzyme Process brand Super Cal-Mag Complex, Food Research brand Pro-Enzymes, and Food Research brand Inflam-Enzymes products are misbranded within the meaning of 21 U.S.C. § 343(q)(5)(F) in that the presentation of the nutrition information on the products' labeling fails to comply with 21 C.F.R. § 101.36(b)(2). For example, Defendants' Enzyme Process brand Adrenucleo and Enzyme Process brand Bone-C-Dent product labels fail to declare the correct name for niacin and

fail to list "HCl" in parentheses after thiamin to indicate its source, as required under 21 C.F.R. § 101.36(d);

E. Defendants' Enzyme Process brand Black Cohosh w/Enzymes, Enzyme Process brand Saw Palmetto W/Enzymes, Enzyme Process brand Glucosamine/Chondroitin, 60 Tablets, Enzyme Process brand RearPlex, Enzyme Process brand Digeszyme-V, 120 Capsules, Enzyme Process brand Glucosamine/Chondroitin, 90 Capsules, and Enzyme Process brand Antioxyme products are misbranded within the meaning of 21 U.S.C. § 343(q)(1)(A) in that the product labels fail to list the correct serving size, as required under 21 C.F.R. §§ 101.9(b) and 101.12(b);

F. Defendants' Enzyme Process brand MSM Glucosamine with Bromelain, Enzyme Process brand Glucosamine/Chondroitin, 60 Tablets, and Enzyme Process brand Glucosamine/Chondroitin, 90 Capsules and 180 Capsules products are misbranded within the meaning of 21 U.S.C. § 343(w) in that the product labels declare the allergen shellfish as the source of glucosamine sulfate in the products but fail to identify the species of the shellfish; and

G. Defendants' Dr. Dale's Wellness Center brand Whole Body & Immune Pro product is misbranded within the meaning of 21 U.S.C. § 343(y) in that the product label fails to bear a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event with such dietary supplement.

15. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of food (dietary supplements) that are misbranded within the meaning of 21 U.S.C. § 343.

16. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 343.

Unapproved New Drugs

17. The Act's definition of drug includes products that are "intended for use in

the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B).

18. Because a product's intended use determines whether it is a drug, a product that falls within the Act's dietary supplement definition may also meet the Act's drug definition if it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. *See* 21 U.S.C. § 321(ff).

19. Defendants cause certain of their products to be drugs under the Act because they make claims establishing that the products are intended to cure, mitigate, treat, or prevent diseases ("disease claims").

20. FDA reviewed several of Defendants' products as recently as August 2021, and identified the following claims (italicized below):

A. Infla-Life 90 Capsules: *"Infla-Life Formula represents a combination of enzymes showing biological activity against inflammation…unique combination of nature's most useful anti-inflammatory compounds may help reduce chronic inflammation and pain."* [at http://enzymeprocess.co/];

B. Pancreas 523 100 Tablets: *"…maximum diabetic nutritional support…"* [at http://enzymeprocess.co/];

C. Candida Stop 60 Capsules: *"…may be the root cause of gastrointestinal inflammation which can delay in healing the intestines. This may lead to more infection and more importantly increased inflammation…some doctors believe that a Candida Albicans overgrowth triggers irritable bowel disease."* [at http://enzymeprocess.co/];

D. Colloidal Silver 10ppm: *"…antibiotic/anti-viral/anti-fungal…"*;

E. Enzyme Process brand Chewable Bovine Colostrum for Kids: *"This early concentrated liquid is full of…that anti-microbial substance called Lactoferrin."*;

F. Lidtke Medical brand L-Glutamine Gastrointestinal Formula: *"Formulated to:…Support G.I.…repair…[r]elieve occasional irritable bowel symptoms…"*;

G. Food Research brand Pro-Enzymes: *"Probiotics and herbs ... help relieve an upset stomach…"*; and

H. Food Research brand Probio-Zyme-YST: "*Probiotics and herbs ... help relieve an upset stomach…"*.

21. The claims described in paragraph 20 above are disease claims and demonstrate that the products are intended to cure, mitigate, treat, and/or prevent disease; therefore, certain of Defendants' products are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B).

22. A drug is a "new drug" if "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a product to be deemed "generally recognized as safe and effective" ("GRAS/E"), it must have substantial evidence of safety and effectiveness or, if it is an over-the-counter ("OTC") drug, it must comply with a monograph established by FDA regulation. *See* 21 U.S.C. § 355(d); 21 C.F.R. § 330.1.

23. Defendants' drugs listed in paragraph 20 above lack substantial evidence of safety and effectiveness. There are no published adequate and well-controlled investigations to show that these drugs are GRAS/E for any use and, therefore, qualified experts cannot come to a consensus of opinion concerning the effectiveness of these products.

24. FDA regulations contain OTC monographs that provide a mechanism for certain OTC drugs to be categorized as GRAS/E and thus exempt from the Act's definition of a new drug. *See* 21 C.F.R. § 330.1. An OTC product manufactured and labeled in accordance with an OTC monograph can be marketed without the submission and approval of a new drug application or an abbreviated new drug application. Any drug that does not strictly conform to each of the conditions contained in an applicable monograph, however, is subject to the new drug provisions of the Act.

25. Defendants' drugs listed in paragraph 20 above do not conform to any OTC monograph and, thus, are not GRAS/E by regulation.

26. Because Defendants' drugs are not GRAS/E, they are new drugs.

27. A drug that is a "new drug" within the meaning of the Act is prohibited from being introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application or abbreviated new drug application for that drug, or the drug is exempt from approval. *See* 21 U.S.C. §§ 355(a), (b), and (j).

28. FDA searched its records and found no new drug applications or abbreviated new drug applications, or investigational new drug applications for Defendants' new drugs listed in paragraph 20 above. Defendants' products are therefore unapproved new drugs within the meaning of the Act, 21 U.S.C. § 355(a), and are not exempt from the Act's approval requirements for new drugs.

29. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval.

Misbranded Drugs

30. A drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use" and it does not fall within a regulatory exemption from that requirement. FDA has defined "adequate directions for use" as "directions under which the layman can use a drug safely and for the purpose for which it is intended." 21 C.F.R. § 201.5(a).

31. Drugs that are unapproved are not exempt from the requirement for adequate directions for use. *See* 21 C.F.R. §§ 201.100(c)(2), 201.115.

32. It is not possible to write adequate directions for use for Defendants' drugs because such directions -- including dosages, indications, contraindications, warnings, side effects, and necessary collateral measures -- are premised on animal and clinical data derived from extensive, scientifically controlled testing. As noted in paragraph 23 above,

there are no well-controlled clinical test data for Defendants' drugs.

33. Certain of Defendants' drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because they fail to bear adequate directions for use. These drugs are not exempt from the requirement for adequate directions for use because they are unapproved. *See* 21 C.F.R. §§ 201.100(c)(2), 201.115.

34. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

35. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

Previous Violations

36. Defendants have previously violated the Act, as documented by FDA investigators during inspections of Defendants' Facility conducted in 2012, 2014, 2016, and 2019. During each of these prior inspections, FDA investigators:

A. Observed Dietary Supplement CGMP deviations that were the same or similar to the observations made during FDA's most recent inspection (described in paragraph 10 above);

B. Identified numerous claims on Defendants' website and product labels that established that certain of their products were intended to be used to cure, mitigate, treat, or prevent diseases; and

C. Identified that Defendants' products labeling failed to comply with the labeling requirements for dietary supplements.

37. FDA has repeatedly warned Defendants about their ongoing violations. At the close of FDA's 2019 and 2021 inspections, FDA investigators issued a List of Inspectional Observations ("Form FDA-483") to, and discussed each of the observed Dietary Supplement CGMP deviations with, Defendant Roderick. At the close of FDA's 2012, 2014, and 2016 inspections, FDA investigators issued Forms FDA-483 to Global

Vitality's Manager, Ms. Diane M. Happy. During each inspection, except for the 2021 inspection, FDA investigators also spoke with Defendant Roderick, Ms. Happy, or Defendant Blagojevic about the numerous claims on Defendants' website and product labels that cause their products to be drugs within the meaning of the Act and the deficiencies with their products' labeling.

38. On January 2, 2020, FDA issued a Warning Letter to Defendant Roderick informing him that Defendants were introducing into interstate commerce unapproved new drugs/misbranded drugs and adulterated and misbranded dietary supplements.

39. On October 19, 2018, FDA issued an Untitled Letter to Defendant Roderick informing him that Defendants were introducing into interstate commerce unapproved new drugs and misbranded drugs, including Defendants' Colloidal Silver 10ppm product.

40. Defendant Roderick has repeatedly promised to correct the Dietary Supplement CGMP deficiencies observed by FDA, to remove the disease claims from his website, and to relabel products.

41. Moreover, Defendants failed to follow through on promises to correct their Dietary Supplement CGMP violations, as shown by the FDA investigators' observations and documentation of ongoing repeat CGMP deficiencies during the 2021 inspection.

42. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, cease receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing articles of dietary supplement and/or articles of drug, unless and until:

A. Defendants' facilities, methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements are established, operated, and administered in conformity with Dietary Supplement CGMP

and the Act, in a manner acceptable to FDA;

B. Defendants' dietary supplement labeling complies with 21 U.S.C. § 343 and applicable regulations, in a manner acceptable to FDA; and

C. Defendants' claims do not cause any dietary supplement or purported dietary supplement that they receive, manufacture, prepare, pack, repack, label, hold, or distribute to be a drug within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B), unless and until the product is the subject of an approved new drug application or abbreviated new drug application, 21 U.S.C. §§ 355(a), (b), and (j), or is exempt from approval..

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered or introduction, into interstate commerce articles of food (including but not limited to dietary supplements and their components) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343;

B. Violating 21 U.S.C. § 331(k), by causing articles of food (including but not limited to dietary supplements and their components) that are held for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343;

C. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1);

D. Violating 21 U.S.C. § 331(k), by causing articles of drug that are held for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

E. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval.

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place of business and all records relating to the receipt, manufacture, preparing, packing, labeling, holding, and distribution of all of Defendants' products to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

IV. Order that Plaintiff be awarded costs incurred in pursuing this action and such other equitable relief as the Court deems just and proper.

Respectfully submitted this __ day of _____, 2022.

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