CV 13-00635LEK-KSC

[✔] ORDER SETTING RULE 16 SCHEDULING CONFERENCE

[] ORDER SETTING STATUS CONFERENCE

for **Monday, February 10, 2014** at 9:00 a.m. before:

[] Magistrate Judge Barry M. Kurren in Courtroom 7

[✔] Magistrate Judge Kevin S.C. Chang in Courtroom 5

[] Magistrate Judge Richard L. Puglisi in Courtrooom 6

Pursuant to Rule 16 of the Federal Rules of Civil Procedure ("Fed.R.Civ.P.") and Local Rule 16.2 of the Rules of the United States District Court for the District of Hawaii:

- Parties are reminded that, unless otherwise ordered by the Court, a meeting of the parties must occur at least 21 days prior to the Scheduling Conference and a report submitted to the Court. Except as otherwise provided by L.R. 26.1(c), no formal discovery may be commenced before the meeting of the parties.
- Each party shall file a Scheduling Conference Statement pursuant to L.R. 16.2(b), and shall attend in person or by counsel.
- Failure to file and/or attend will result in imposition of sanctions, (including fines or dismissal), under Fed.R.Civ.P. 16(f) and L.R. 11.1.

DATED at Honolulu, Hawaii on Tuesday, November 19, 2013.

/s/ Susan Mollway
Chief, U.S. District Judge

I hereby acknowledge receipt of the Order Setting Rule 16 Scheduling Conference.

Date November 19, 2013 Signature

Atty ( ) Secy ( ) Messenger ( )

THIS SCHEDULING ORDER IS ATTACHED TO THE INITIATING DOCUMENT (COMPLAINT/NOTICE OF REMOVAL) & MUST BE SERVED WITH THE DOCUMENT. PLEASE DO NOT REMOVE.

UNITED STATES DISTRICT COURT
DISTRICT OF HAWAII
OFFICE OF THE CLERK
300 ALA MOANA BLVD., RM C-338
HONOLULU, HAWAII 96850

TEL (808) 541-1300
FAX (808) 541-1303

Sue Beitia
CLERK

MEMO

To: All Federal Bar Members

From: Sue Beitia, Clerk of U.S. District Court, District of Hawaii

Date: November 19, 2013

Subject: Corporate Disclosure Statements

Federal Rule of Civil Procedure 7.1 and Criminal Rule 12.4 both address the filing of Corporate Disclosure Statements.

Both rules state "A party must:

(1) file the Rule 7.1(a) *(or 12.4(a))* statement with its first appearance, pleading, petition, motion, response, or other request addressed to the court, and

(2) promptly file a supplemental statement upon a change in the information that the statement requires."

Thank you for your cooperation in this matter.

OGAWA, LAU, NAKAMURA & JEW
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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

EVERINE VAN HOUTEN, a single person, Plaintiff, vs. USPlabs, LLC, a Texas corporation, and GNC Holdings, Inc., a Pennsylvania corporation, Defendants. 7939-001	CIVIL NO. CV13 00635 LEK KSC **COMPLAINT**; Summons

COMPLAINT

OMES NOW Plaintiff, EVERINE VAN HOUTEN, by and through her counsel of record, MICHAEL O'CONNOR of OGAWA, LAU, NAKAMURA & JEW, and alleges and complains as follows:

I.

PARTIES

1.1 Plaintiff resides in Hawaii County, Hawaii.

1.2 Defendant USPlabs LLC ("USP") is a Texas based manufacturer of a wide variety of dietary supplements, including specifically OxyElite Pro ("the Product"), a protein supplement marketed and sold as beneficial for muscle increase and weight loss. OxyElite Pro was manufactured by Defendant USP in several formulations, and sold in both power and tablet form. As stated by Defendant USP, several formulations of the Product has now been recalled by it after epidemiological and traceback investigation by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") showed that use of the Product has been associated with serious adverse health consequences, namely serious liver damage and/or acute liver failure. See http://www.fda.gov/Safety/Recalls/ucm374394.htm checked November, 2013).

1.3 Defendant GNC Holdings, Inc. ("GNC") is a global retailer of health, sports nutrition, and diet products. At all times material hereto, Defendant GNC knowingly distributed and sold the Product in GNC retail stores locations in the State of Hawaii.

II.

JURISDICTION AND VENUE

2.1 Defendants have engaged in substantial, continuous, and systematic contacts within the State of Hawaii, purposefully directing their activities towards Hawaii, including the placement of their goods into the stream of commerce with the intent and expectation they will be purchased by consumers in Hawaii, and this litigation arises out of those activities; and (b) venue would be proper in Hawaii because the facts giving rise to one of the Plaintiff's' claims arose in Hawaii, and Plaintiff was injured in Hawaii.

2.2 This court is vested with jurisdiction over the Defendants pursuant to 28 U.S.C. § 1332. The amount of controversy exceeds $75,000.00 exclusive of interests and costs, and this is an action against Defendants with their principal places of business in other states.

2.3 Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.

III.

THE NATURE OF THE ACTION

3.1 This is a personal injury lawsuit brought on behalf of Plaintiff who suffered injuries, including acute non-viral hepatitis as a result of consumption

of OxyElite Pro tablets manufactured and distributed by Defendant USP, and sold by Defendant GNC. The Product was manufactured, distributed, and sold by the Defendant USP, through Defendant GNC stores in Hawai'i.

3.2 As a result of her consumption of the Product, Plaintiff experienced hepatic injury and associated symptoms including pain, fatigue, malaise, nausea, anorexia which required multiple medical treatments, hospitalization, and possible long-term liver damage.

IV.

OTHER FACTUAL ALLEGATIONS

5.1 On September 9, 2013, the Hawaii Department of Health ("DOH") was notified of seven patients with severe acute hepatitis and sudden liver failure of unknown cause. These patients were previously healthy. Doctors reported that all seven patients had consumed Defendant USP's product OxyElite Pro marketed for weight loss and muscle gain prior to onset of their illnesses.

5.2 To date, clinicians have reported at least 45 patients to Hawaii DOH in response to a public health alert. Of those, 24 patients, including the original seven, have been confirmed to have acute hepatitis after using OxyElite Pro during the 60 days before illness onset.

5.3 On or about October 11, 2013, the FDA notified Defendant USP that its OxyElite Pro products which contained aegeline may be deemed adulterated because they contain a new dietary ingredient for which there was inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

5.4 On November 9, 2013, the FDA announced that Defendant USP was voluntarily conducting a national recall of all lots and sizes of the OxyElite Pro dietary supplement. The FDA indicated that epidemiological evidence showed that use of these products had been associated with serious adverse health consequences, namely serious liver damage or acute liver failure, concentrated in Hawaii.

5.5 On or about November 9, 2013, Defendant USP recalled some of its OxyElite Pro products, and Defendant GNC stores removed those products from store shelves. The products Defendant USP recalled included various forms of OxyElite Pro Super Thermo capsules; OxyElite Pro Ultra-Intense Thermo capsules and OxyElite Pro Super Thermo Powder.

Defendant USP stated that the recalled products contained Aegeline, a synthesized version of a natural extract from the Bael tree. Aegeline is not approved by the FDA as a dietary supplement. The Defendant USP's recall was initiated after it was notified by the FDA that its OxyElite products had been linked to cases of liver injury in Hawai'i and that there was a reasonable probability that the products were adulterated.

5.6 On or about February 5, 2013 Plaintiff purchased OxyElite Pro tablets from Defendant GNC's store located in the Prince Kuhio Plaza in Hilo,

Hawai'i. Plaintiff purchased two containers of OxyElite Pro and additionally received two sample sized containers of a "new" formulation of OxyElite Pro as part of her purchase. At the time, Plaintiff was not aware that the consumption of the OxyElite Pro product could, and would, cause her and others illness and injury.

5.7 The Plaintiff consumed both the regular OxyElite Pro tablets and the "new" formulation of OxyElite Pro over the ensuing months. Beginning in or about March 2013 the Plaintiff began to experience symptoms of abdominal pain, nausea, fatigue and muscle aches for which she ultimately sought medical attention in Hilo, Hawaii. The Plaintiff's symptoms recurred in April which caused her to seek treatment in an emergency room.

Plaintiff's symptoms throughout the summer months of 2013 recurred and caused her to be hospitalized in August at the Hilo Medical Center.

Plaintiff was diagnosed with acute hepatitis due to an unknown cause. Plaintiff underwent numerous tests and medical procedures in an effort to determine the nature and extent of her liver illness.

5.8 During 2013, the Plaintiff was employed as a clerk at the Hilo Medical Center. On or about September, 2013 Plaintiff saw a public health

notice advising of a possible link between cases of acute hepatitis and OxyElite Pro products. Subsequently Plaintiff was interviewed by DOH concerned her consumption of the Product and her liver injuries.

5.9 As a result of Plaintiff's acute hepatitis and relating symptoms and medical care, Plaintiff was unable to work through much of 2013. The Plaintiff continues to undergo testing and medical monitoring of her liver and continues to experience symptoms related to her liver injury.

VI.
FIRST CAUSE OF ACTION
(Strict Liability)

6.1 By this reference, Plaintiff incorporates the preceding paragraphs of this complaint as if each and every of these paragraphs was set forth here in its entirety.

6.2 Defendants USP and GNC manufactured and sold the Product that has been identified by the CDC as the potential cause of at dozens illnesses in Hawaii, as described previously, and that caused the Plaintiff to suffer liver damage.

6.3 Because Defendants' Product was unsafe for human consumption and caused hepatic injury, the Product that the Defendants manufactured and sold to Plaintiff was in a condition that Plaintiff had not contemplated, and was in a condition that rendered the Product unreasonably dangerous for its reasonably foreseeable use.

6.4 The food that Defendants manufactured and sold to Plaintiff was expected to reach Plaintiff, and to be consumed by her, without substantial change. Plaintiff used the Product in the manner expected and intended, when she consumed it.

6.5 Plaintiff suffered the aforementioned injuries as a direct and proximate result of the contaminated, defective food manufactured and sold by Defendants.

VII.

SECOND CAUSE OF ACTION

(Negligence)

7.1 By this reference, Plaintiff incorporates the preceding paragraphs of this complaint as if each and every of these paragraphs was set forth here In its entirety.

7.2 Defendants USP and GNC manufactured, distributed, and sold a food Product that was potentially adulterated, not fit for human consumption, and that was not reasonably safe as designed, manufactured, or sold.

7.3 Defendants were negligent in manufacturing, distributing, and selling a food Product that was adulterated, not fit for human consumption, and not reasonably safe because it contained an ingredient injurious to human health and because adequate warnings or instructions were not provided, including but not limited to the warning that the Product may contain ingredients not approved by FDS for dietary supplements and thus should not be given to, or eaten by humans.

7.4 Defendants had a duty to properly supervise, train, and monitor their employees, or the employees of their agents or subcontractors, engaged in the preparation of the Product, to ensure compliance with Defendants' operating standards and to ensure compliance with all applicable health regulations. Defendants failed to properly supervise, train, and monitor their employees, or the employees of their agents or subcontractors engaged in the manufacture, preparation and delivery of the Product, and thus breached that duty.

7.5 Defendants owed a duty to Plaintiff to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling, and sale of the Product including all applicable local, state, and federal health and safety regulations. Defendants, by their manufacture, distribution, storage, labeling, and sale of adulterated, unsafe, and unhealthy food Products to Plaintiff, failed to conform to this duty.

7.6 Defendants owed Plaintiff the duty to exercise reasonable care in the sale of the Product, to ensure that the Product it sold to Plaintiff was not adulterated, and was not potentially injurious to human health. Defendants also owed Plaintiff the duty to provide adequate warnings and instructions for the use of the Product. Defendants breached that duty, and thereby caused injury to Plaintiff.

7.7 Defendants breached the aforementioned duties as alleged herein, which breach constituted the proximate cause of Plaintiff's injuries.

VIII.

THIRD CAUSE OF ACTION

(Breach of Warranties)

8.1 By this reference, Plaintiff incorporates the preceding paragraphs of this complaint as if each and every of these paragraphs was set forth here in its entirety.

8.2 Defendants USP and GNC manufactured and sold the Product which Plaintiff purchased.

8.3 Both Defendants impliedly warranted that the food Product sold was fit for the ordinary purpose for which the food Product is used.

8.4 Both Defendants impliedly warranted that the lettuce was of merchantable quality, and was safe and fit for human consumption. Plaintiff purchased the Product, and reasonably relied upon the skill and judgment of Defendants as to whether the Product was of merchantable quality and fit for human consumption.

8.5 Both Defendants expressly warranted that the food Product was safe to eat, and that the food Product had been safely manufactured.

8.6. Defendants breached these implied and express warranties in that Defendants' food Product contained an ingredient injurious to human health, and because adequate warnings or instructions were not provided, including but not limited to the warning that the Product may contain ingredients not approved by FDS for dietary supplements and thus should not be given to, or eaten by humans.

8.7 As a direct, legal and proximate result of the breach of these implied and express warranties, Plaintiff suffered and may continue to suffer injury, harm, special damages and economic loss.

IX.

DAMAGES

9.1 By this reference, Plaintiff incorporates the preceding paragraphs of this complaint as if each and every of these paragraphs was set forth here in its entirety.

9.2 Plaintiff has suffered general and special, incidental and consequential damages as the direct and proximate result of the acts and omissions of Defendants, which damages shall be fully proven at the time of trial. These damages include, but are not limited to: damages for wage loss; medical and medical-related expenses; travel and travel-related expenses; emotional distress; physical pain; physical injury; and all other ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

(1) That the Court award Plaintiff, judgment against Defendants, in such sums as shall be determined to fully and fairly compensate them for all general, special, incidental and consequential damages incurred, or to be incurred, as the direct and proximate result of the acts and omissions of Defendants, in an amount to be proven at trial;

(2) That the Court award Plaintiff her respective costs, disbursements and reasonable attorneys' fees incurred;

(3) That the Court award Plaintiff the opportunity to amend or modify the provisions of this complaint as necessary or appropriate after additional or further discovery is completed in this matter, and after all appropriate parties have been served; and

(4) That the Court award Plaintiff such other and further relief as it deems necessary and proper in the circumstances.

DATED: Honolulu, Hawaii, November 19 2013.

MICHAEL F. O'CONNOR
Attorney for Plaintiff
EVERINE VAN HOUTEN

UNITED STATES DISTRICT COURT

for the

District of Hawaii

EVERINE VAN HOUTEN

Plaintiff

v.

USPlabs, LLC., a Texas corporation, and GNC Holdings, Inc., a Pennsylvania corporation

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* USPlabs, LLC., a Texas corporation
10761 King William Drive
Dallas, Texas 75220-2445

GNC Holdings, Inc., a Pennsylvania corporation
300 6th Avenue
Pittsburg, Pennsylvania 15222

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

MICHAEL F. O'CONNOR, ESQ.
Ogawa Lau Nakamura & Jew
600 Ocean View Center, 707 Richards Street
Honolulu, Hawaii 96813

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

SUE BEITIA
CLERK OF COURT

Date: NOV 19 2013

/s/ Della Geronimo
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc: