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FILED IN THE
UNITED STATES DISTRICT COURT
DISTRICT OF HAWAII
NOV 19 2013
at 3 o'clock and 30 min. P.M. *MD*
SUE BEITIA, CLERK

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. 013 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:

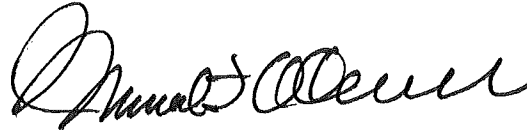
(1) That the Court award Plaintiff, judgment against Defendants, in such sums as shall be determined to fully and fairly compensate them for all general, special, incidental and consequential damages incurred, or to be incurred, as the direct and proximate result of the acts and omissions of Defendants,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

HID 440 (Rev. 12/09) Summons in a Civil Action

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

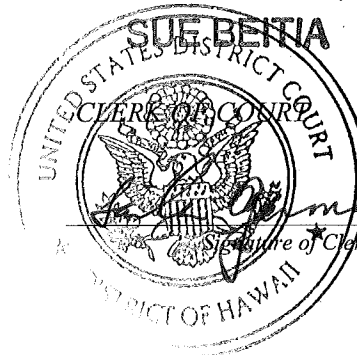
A lawsuit has been filed against you.

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.

Date: NOV 19 2013



Signature of Clerk or Deputy Clerk

AO 440 (Rev. 12/09) Summons in a Civil Action (Page 2)

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:

JS 44 (Rev. 12/12)

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS EVERINE VAN HOUTEN, a single person

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)
Michael F. O'Connor, #1098
Ogawa, Lau, Nakamura & Jew, 600 Ocean View Ctr.
Honolulu, Hawaii 96813
TELEPHONE: (808) 533-3999

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

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

1 U.S. Government Plaintiff

2 U.S. Government Defendant

3 Federal Question (U.S. Government Not a Party)

4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4
Citizen of Another State	<input type="checkbox"/> 2	<input checked="" type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act (Excludes Veterans) <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

1 Original Proceeding

2 Removed from State Court

3 Remanded from Appellate Court

4 Reinstated or Reopened

5 Transferred from Another District (specify)

6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. Sections 1332 and 1391(a)(2)

Brief description of cause:
Sale and marketing of unsafe food

VII. REQUESTED IN COMPLAINT:


CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$ _____

CHECK YES only if demanded in complaint:
JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY (See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE 11/19/2013 SIGNATURE OF ATTORNEY DE BELORE 

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____