U.S. FOOD & DRUG ADMINISTRATION

VIA E-MAIL

Kieu Hoang, Chief Executive Officer
RAAS Nutritionals, LLC
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Re: Submission of Clinical Trial Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2022-101

Dear Mr. Hoang:

Based on an initial review of Food and Drug Administration (FDA) records and any available public information, it appears that RAAS Nutritionals, LLC, is the "responsible party"[1] for the below-identified clinical trials, which appear to be "applicable clinical trials"[2] subject to the requirements of section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11. A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank: (1) certain registration information regarding an applicable clinical trial within 21 days after the first patient is enrolled in the clinical trial,[3] and (2) certain results information for such clinical trial, which generally must be submitted no later than one year after the primary completion date[4] of the applicable clinical trial, unless the responsible party has submitted a timely

[1] *See* section 402(j)(1)(A)(ix) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(1)(A)(ix)) and 42 CFR 11.10 for the definition of "responsible party."
[2] *See* section 402(j)(1)(A)(i) - (iii) of the PHS Act (42 U.S.C. 282(j)(1)(A)(i) - (iii)) and 42 CFR 11.10 for the definition of "applicable clinical trial."
[3] *See* section 402(j)(2)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(2)(C)(ii)) and 42 CFR 11.24 for registration requirements.
[4] *See* 42 CFR 11.10 for the definition of "primary completion date." *See also* section 402(j)(1)(A)(v) of the PHS Act (42 U.S.C. 282(j)(1)(A)(v)), which defines "completion date." As reflected in 42 CFR 11.10, the terms "primary completion date" and "completion date" are synonymous for purposes of 42 CFR part 11.

certification of delay, request for an extension for good cause, or request for a waiver of the requirements for submission of results information.[5]

FDA has identified potential noncompliance related to the following clinical trials:

- "Efficacy of novel functional food supplements based on grape, soy, edamame and rice in the prevention, treatment and cure of COVID-19 and 315 viruses and bacteria, including 116 other viruses and bacteria and 198 SARS-CoV-2 mutation and non-otherwise specified viruses and bacteria (NOS)"[6]

  This study evaluated the effect of Kunamin®,[7] KHJ®,[8] KHJ-R®,[9] and Kunakinmin®[10] on symptom improvement, SARS-CoV-2 viral load, and detection of SARS-CoV-2 ribonucleic acid on molecular assay in subjects who tested positive for COVID-19.

- "A Prospective, Open-label, Observational Study of The Efficacy of Kunamin® (a grape derived supplement US Patent US 10,195,243 B2) on Subjects with Chronic Hepatitis B. These HBV subjects may have concomitant diabetes mellitus type 2 (DM II), obesity, hypertension, chronic kidney disease, and/or hypercholesterolemia, and they are on stable standard therapy/drug for the respective condition"

  This study evaluated the effect of Kunamin® on the reduction or eradication of hepatitis B (HBV) viral DNA titer in subjects who tested positive for HBV.

- "A Prospective, Open-label, Observational Study of The Efficacy of Kunakin® (a soybean and rice derived supplement US Patent Application Serial No. 14/979,697 and No. 62/304,434) on Subjects with Chronic Hepatitis C. These HCV subjects may have concomitant diabetes mellitus type 2 (DM II), obesity, hypertension, chronic kidney disease, and/or hypercholesterolemia, and they are on stable standard therapy/drug for the respective condition"

  This study evaluated the effect of Kunakin®[11] on the reduction or eradication of hepatitis C (HCV) viral RNA titer in subjects who tested positive for HCV.

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[5] *See* section 402(j)(3)(E) and (H) of the PHS Act (42 U.S.C. 282(j)(3)(E) and (H)) and 42 CFR part 11, subpart C for results information submission requirements.
[6] Coronavirus Disease 2019 (COVID-19) is the respiratory disease caused by the novel coronavirus called *Severe Acute Respiratory Syndrome Coronavirus 2* (SARS-CoV-2).
[7] Proprietary blend of wine grape powder and grape seed powder.
[8] Proprietary blend of dealcoholized wine and grape juice concentrate.
[9] Proprietary blend of red wine powder, grape powder, grape juice concentrate, and wine and rice concentrate.
[10] Proprietary blend of wine, soy powder, edamame powder, grape powder, grape seed extract, grape juice concentrate powder, and soylac powder.
[11] Proprietary blend of wine, soy powder, and soy isoflavones.

It appears that registration information for the above-referenced applicable clinical trials has not been submitted to the ClinicalTrials.gov data bank. Your company should review its records of these clinical trials and determine whether your company submitted all required registration information for these clinical trials. If your company determines that clinical trial registration information should be submitted, please submit it promptly. Your company should also determine whether results information is required and due for these clinical trials and, if so, should submit the results information promptly.

Failure to submit clinical trial information[12] required under section 402(j) of the PHS Act (42 U.S.C. 282(j)), including information required under the regulations found in 42 CFR part 11, is a prohibited act under section 301(jj)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 331(jj)(2)). Beginning 30 calendar days after you receive this letter, FDA intends to further review and assess the above-identified clinical trials. If FDA determines that your company has failed to submit any clinical trial information required under section 402(j) of the PHS Act (42 U.S.C. 282(j)), including its implementing regulations in 42 CFR part 11, your company may receive from FDA a Notice of Noncompliance,[13] and FDA may thereafter initiate an administrative action seeking a civil monetary penalty.[14] In addition to civil monetary penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. 331(jj)) could also result in other regulatory action, such as injunction and/or criminal prosecution, without further notice.

As requested, please review your company's clinical trial records and submit any required clinical trial registration and results information to the ClinicalTrials.gov data bank. You can access the ClinicalTrials.gov website at https://register.clinicaltrials.gov. If you have any questions about this letter, you may call Miah Jung, Pharm.D., at (240) 402-3728. Please have the FDA reference number provided at the top of this letter available when you call. Alternatively, you may e-mail FDA at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications.

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[12] *See* section 402(j)(1)(A)(iv) of the PHS Act (42 U.S.C. 282(j)(1)(A)(iv)) and 42 CFR 11.10 for the definition of "clinical trial information."

[13] *See* section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)).

[14] Pursuant to section 303(f)(3)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 333(f)(3)(A)), "[a]ny person who violates section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding." "If a violation of section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] is not corrected within the 30-day period following [receipt of a statutory Notice of Noncompliance under section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii))], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected." *See* Section 303(f)(3)(B) of the FD&C Act (21 U.S.C. 333(f)(3)(B)). These civil monetary penalty amounts reflect the amounts found in the statute. These amounts are updated annually to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. No. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461, note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, November 2, 2015). For the most up-to-date amounts, please see 45 CFR 102.3.

We request that you submit a written response to FDA within 30 calendar days after you receive this letter, stating the actions you have taken in response to this letter. If you believe that your company has complied with applicable requirements, please provide us with your reasoning and include any supporting information for our consideration. Please direct your response to the address below and include the FDA reference number in all correspondence relating to this matter.

Miah Jung, Pharm.D., M.S.
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Division of Enforcement and Postmarketing Safety
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
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10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely yours,

Laurie B. Muldowney -S

Digitally signed by Laurie B. Muldowney -S
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Laurie Muldowney, M.D.
Deputy Director
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