

**WARNING LETTER****Results RNA, LLC****MARCS-CMS 540501 – APRIL 06, 2018****Recipient:**

Results RNA, LLC  
United States

**Issuing Office:**

Denver District Office  
United States



Denver District Office  
5th Ave & Kipling St, DFC Bldg 20  
P.O. Box 25087  
Denver, CO 80225

**WARNING LETTER**

April 6, 2018

**VIA UPS Overnight**

Mr. David L. Larson, CEO  
Mr. Brian G. Larson, CFO  
Results RNA, LLC  
1272 S. 1380 W.  
Orem, UT 84058

Ref: # HAF4W(DEN)-18-08-WL

Dear Mr. D. Larson and Mr. B. Larson:

On August 3, 2017 through August 9, 2017, the U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 1272 S. 1380 W., Orem, Utah. During our inspection, we collected product labels for products you manufacture and distribute. Your website at the Internet address [www.resultsrna.com](http://www.resultsrna.com) was also reviewed. During our review of your product labels collected during the inspection, as well as our review of your firm's website, we found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable

regulations. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at [www.fda.gov](http://www.fda.gov) (<http://www.fda.gov/>).

### Unapproved/Misbranded New Drugs

The FDA reviewed your website at the Internet address [www.resultsrna.com](http://www.resultsrna.com) in April 2018 and has determined that you take orders there for products, including Ultimate Lyme Support Extra Strength, ACS 200 Extra Strength, ACJ Joint Extra Strength, ACZ Nano Extra Strength, ACN Neuro Extra Strength, Allergy Care Extra Strength, MRSA Care Extra Strength, ACS 200 Silver Gel Extra Strength, ACS Nasal Extra Strength, and Lubrisine Eye Drops Extra Strength. FDA also reviewed product labels, including labels for your Ultimate Lyme Support Extra Strength, Allergy Care Extra Strength, ACS 200 Silver Gel Extra Strength, Lubrisine Eye Drops Extra Strength, ACZ Nano Extra Strength, Ultimate Body Detox Extra Strength, and Rash Care Extra Strength products following an inspection of your facility between August 3, 2017 and August 9, 2017. We have determined that the claims on your website and product labels establish that the products are drugs under section 201(g)(1)(B) of the Act [21 U.S.C. 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the website and product label claims that provide evidence that your products are intended for use as drugs include:

#### Ultimate Lyme Support Extra Strength

Note: this is a combination product. Kit includes ACS Extra Strength, ACZ Nano Extra Strength, ACN Neuro Extra Strength and ACG Glutathione Extra Strength.

Website:

- “ACS 200 Extra Strength...Broad-spectrum Antimicrobial...ACS 200 Extra Strength achieves 99.9999% (complete) kill against *Borrelia burgdorferi*, *Bartonella henselae* and co-infection microorganisms Powassan virus, MRSA and more without harming healthy flora or damaging human tissue. Results are fast acting and safe and recommended by Lyme literate doctors worldwide . . .”
- “ACZ Nano Extra Strength...Maximum Detoxification...Pathogens such as Lyme associated *Borrelia burgdorferi* require a toxic host to survive. Boost your immune system and achieve long term health by cleansing your body of immunocompromizing toxic heavy metals and more . . .”
- “ACN Neuro Extra Strength...Neurological System Rejuvenation...ACN Neuro Extra Strength effectively reduces neurological manifestations associated with Lyme disease. . .”
- “I was diagnosed almost 5 years ago with Lyme . . . I have only had 2 months of treatment and can tell a significant difference in the way I feel . . .”
- “A powerful oral detoxification agent, ACZ nano selectively and irreversibly binds and excretes toxic heavy metals, such as Mercury and Lead, chemical toxins, radioactive toxins and free radicals via the urinary tract . . . These results have been verified in multiple, independent urine challenge studies. Removing damaging toxins is vital for Lyme sufferers if health is to be restored . . .”

Product label:

- “[H]eals and rejuvenates while minimizing herxheimer reaction . . . Kills *Borrelia burgdorferi* . . . Kills *Bartonella henselae* . . . Proven to kill disease causing microorganisms . . . Detoxifies the entire body . . .”

#### ACS 200 Extra Strength

Website:

- “Superior Silver Kills pathogens... Effective against an enormous array of disease causing organisms; including bacteria, spirochetes, virus, fungus, parasites & more... proven to achieve 99.9999% (complete) kill against 660 microorganisms; including *Borrelia burgdorferi*, *Bartonella henselae*, Powassan virus, Rhinovirus, *Legionella pneumophila*, *Pseudomonas aeruginosa*, *Salmonella bongori*, *Candida albicans* & MRSA . . . It relieved my heart valve infection within 2 days when nothing else had.” \* . . . shown to

enhance the efficacy of antibiotics by 1,000x . . . proven the most effective, broad-spectrum antimicrobial available . . .”

#### **ACJ Joint Extra Strength**

Website:

- “[P]rovides significant OA relief . . . ACJ Joint substantially alleviates OA symptoms; exerting anti-inflammatory . . . effect . . .”

#### **ACZ Nano Extra Strength**

Website:

- “ACZ Nano Extra Strength has been shown to increase urinary output of Lead and Mercury up to 103,500% over baseline during only 12 hours of post-provocation urine collection . . .”
- “[E]ffectively reverses acute chemical and allergic reactions . . .”
- “[O]rdered ACZ Nano Extra Strength for Lymedetox, to treat the ongoing headaches . . . I ordered your product and used the lower dose in one 24 hour period. I was shocked by the results! My Lyme headaches have been reduced 90%. And the severity, from severe to mild . . .”
- “ACZ NANO ZEOLITE EXTRA STRENGTH IS THE FIRST AND ONLY INTRACELLULAR DETOXIFICATION AGENT CLINICALLY PROVEN TO REMOVE TOXIC HEAVY METALS AT THE CELLULAR LEVEL . . .”

#### **ACN Neuro Extra Strength**

Website:

- “As diseases such as Lyme or Alzheimer’s progress, they can attack the nervous system, producing learning disabilities . . . memory loss, anxiety and depression . . . obsessive behavior, and other psychiatric diagnoses. ACN neuro reduces mental anxiety and stress; specifically on brain cells while reducing neuroinflammation. . . .”

#### **Allergy Care Extra Strength**

Website:

- “[H]erbal decongestants . . . during all seasons and conditions of allergic response . . .”
- “ALLERGY SEASON CARE EXTRA STRENGTH PROVIDES EXCEPTIONAL ALLERGY SEASON RELIEF . . .”

Product label:

- “Natural decongestant . . .”

#### **MRSA Care Extra Strength**

Website:

- “[S]trengthens immunity, reducing susceptibility and symptoms associated with Staphylococcus aureus . . .”
- “STAPH INFECTION IS A SERIOUS ISSUE. MRSACARE EXTRA STRENGTH PROVIDES POWERFUL IMMUNE SYSTEM SUPPORT TO HELP THE BODY WARD OFF BACTERIA . . .”

Product label:

- “Antibacterial . . .”
- The name of the product

### **Ultimate Body Detox Extra Strength**

Product label:

- “Proven to kill pathogens . . . remove toxic heavy metals . . . Proven to kill disease causing microorganisms . . . Detoxifies the entire body . . .”

### **Rash Care Extra Strength**

Product label:

- “Rash . . . Skin relief . . .”

### **ACS 200 Silver Gel Extra Strength**

Website:

- “[S]ignificant relief from eczema, sunburn, burns, cuts, scrapes, rashes and more for enhanced healing and discernable relief”
- “Recommended Topical Applications[:] 1 Abrasions 2 Acne 3 Age spots 4 Anal irritation 5 Athletes foot 6 Bed bug bites 7 Bee stings 8 Blisters 9 Body odor 10 Broken skin 11 Bruises 12 Bug bites 13 Burns 14 Candidiasis 15 Cat scratches 16 Cellulitis 17 Chaffing 18 Cracked lips 19 Cracked skin 20 Cuts 21 Dandruff 22 Decubitus Ulcers (pressure ulcers) 23 Diaper rash 24 Dog bites 25 Dry cracked heels 26 Dry skin 27 Eczema 28 Edema 29 Foot odor 30 Fungal nail infection 31 Genital irritation 32 Gym burn 33 Hemorrhoids 34 Hives 35 Infected wounds 36 Jock itch 37 lacerations (sic) 38 Mosquito bites 39 MRSA skin infection 40 Nasal boils or zits 41 Nasal skin irritation 42 Nipple irritation 43 Peeling skin 44 Pierce hole redness / irritation 45 Poison Ivy irritation 46 Post dermal scrub 47 Post laser treatment 48 Post plastic surgery 49 Post tattoo 50 Post-intercourse irritation 51 Post-shaving irritation 52 Post-silver removal irritation 53 Post-surgery skin infections 54 Post-surgery skin sutures / stitches 55 Post-surgery wounds 56 Pre-surgery skin treatment 57 Redness 58 Rosacea 59 Rug burn 60 Runner thigh chaffing 61 Sagging skin under eyes 62 Scalp irritation 63 Scarring 64 Scrapes 65 Scratches 66 Shingles sores 67 Skin allergies 68 Skin transplant 69 Skin ulcers 70 Spider bites 71 Sports irritated ands or feet 72 Stinging nettle irritation 73 Stretch marks 74 Sunburn 75 Sunspots 76 Toe fungus 77 Underarm itch 78 Vaginal irritation 79 Warts 80 Wind chapping 81 Wounds 82 Wrinkles”

Product label:

- “Accelerates Dermal Healing”
- “Regenerates Damaged Cells”

### **ACS Nasal Extra Strength**

Website:

- “The ultimate weapon against Flu, Cold and Sinus Infections, providing rapid sinus and congestion relief”
- “Use daily to kill Bacteria and Viruses that can harbor in the sinus cavities.”
- “The only nasal spray proven to kill rhinovirus, the most prevalent virus causing Flu and Colds.”
- “Broad Spectrum Antimicrobial”
- “[K]ills viruses, bacteria... fungus.”

- “It works!! I’ve had lyme and 9 other coinfections since age 15 .. when I used this silver it helped instantly I bought the nasal spray as well just in case I felt it might be a placebo affect I had my father try it who suffers from lyme as well and he was in shock at how well it worked to relieve horrific sinusitis / mold issues ... it does work I’ll never be without it.”

### **Lubrisine Eye Drops Extra Strength**

Product label:

- “For the temporary relief of burning, itching, irritation or dryness of the eye.”

Website:

- “Allergy Eye Relief . . . Lubrisine eye drops provide brilliant allergy season relief as well as focused nutrients directed towards improving the overall health of the eyes . . . Lubrisine eye drops are the first and only eye drop formula to soothe by healing.”

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are “new drugs” under section 201(p) of the Act [21 U.S.C. 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective. With respect to Lubrisine Eye Drops, OTC drug products intended as lubricant eye drops are subject to the final rule for Ophthalmic Drug Products for Over-the-Counter Use, see 21 CFR Part 349. However, this product is not labeled or formulated in accordance with this final rule because it is formulated with ingredients that are not included in this final rule. Furthermore, the final rule states that claims such as the temporary relief of burning and irritation due to dryness of the eye are permissible, however claims outside of these intended uses, such as the ones cited above, are not included in this final rule.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your Ultimate Lyme Support Extra Strength, ACN Neuro Extra Strength, ACS 200 Extra Strength, ACZ Nano Extra Strength, MRSA Care Extra Strength, ACS 200 Silver Gel Extra Strength and ACS Nasal Extra Strength products are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, your Ultimate Lyme Support Extra Strength, ACN Neuro Extra Strength, ACS 200 Extra Strength, ACZ Nano Extra Strength, MRSA Care Extra Strength, ACS 200 Silver Gel Extra Strength and ACS Nasal Extra Strength products fail to bear adequate directions for their intended uses and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. 331(a)].

### **Dietary Supplement Misbranding**

Even if many of your dietary supplement products did not have therapeutic claims which make them unapproved new drugs, they would still be misbranded foods (dietary supplements) under section of 403 of the Act [21 U.S.C. § 343] in that the labels for these products do not comply with the labeling requirements in 21 CFR 101, as follows:

1. Your Ultimate Body Detox Extra Strength and Ultimate Lyme Support Extra Strength products are misbranded within the meaning of section 403(s)(2)(B) of the Act [21 U.S.C. § 343(s)(2)(B)] in that the labels fail to include a statement of identity as a “dietary supplement,” as required by 21 CFR 101.3(g).
2. Your Ultimate Body Detox Extra Strength, Ultimate Lyme Support Extra Strength, ACN Neuro Extra Strength (2 oz), and ACG Glutathione (2 oz) products are misbranded within the meaning of section 403(q)(5)(F) of the Act [21 U.S.C. 343 (q)(5)(F)] in that the presentation of the nutrition information on the labeling of your products do not comply with 21 CFR 101.36. For example, the Supplement Facts labels for your Ultimate Body Detox Extra Strength and Ultimate Lyme Support list (b)(2)-dietary ingredients within the proprietary blend of the ACN Neuro Extra Strength and ACG Glutathione product; for example, zinc, magnesium, or ascorbic acid. Such ingredients may only be listed with other (b)(2)-dietary ingredients if they contain at least 2% of the RDI for the particular dietary ingredient. Likewise, the ACN Neuro Extra Strength (2 oz), and ACG Glutathione (2 oz) products, incorrectly list (b)(2)-dietary ingredients within the proprietary blend.

3. Your Ultimate Body Detox Extra Strength, Ultimate Lyme Support Extra Strength, ACJ Joint Extra Strength, ACG Glutathione Extra Strength, ACG Gluco Extra Strength, ACC Cardio Extra Strength, ACN Neuro Extra Strength, ACM Metabo Extra Strength, ACP Prostate Extra Strength, ACR Regen Extra Strength, ACZ Nano Extra Strength, Allergy Care Extra Strength, ACP Pulmo Extra Strength, Rash Care Extra Strength, Pure Energy Extra Strength, MRSA Care Extra Strength, and Fem Care Extra Strength products are misbranded within the meaning of section 403(i)(2) of the Act in that the product label fails to declare all the common or usual names of each ingredient used as required by 21 CFR 101.36 and 21 CFR 101.4. For example, these products contain the ingredient identified as "Natural Trace Minerals" of "Natural Minerals." This is not the appropriate common or usual name for this ingredient. The name of the mineral is the common or usual name.
4. Your Ultimate Body Detox Extra Strength and Pure Energy Extra Strength products are misbranded within the meaning of section 403(q)(1)(A) of the Act [21 U.S.C. § 343(q)(1)(A)] because the serving size declared on the labels are incorrect. Serving size for a dietary supplement is the maximum amount consumed per eating occasion as recommended on the product label as defined in 21 CFR 101.9(b) and 21 CFR 101.12(b) Table 2. Your Ultimate Body Detox Extra Strength product label "dosage guidelines" states to "Take 12 sprays of each by mouth, twice daily." but your serving size for the ACZ Nano Extra Strength product component states "6 sprays." Your Pure Energy Extra Strength product label "Directions for Use" states to "Take 12 sprays by mouth, twice daily." but your serving size states "6 sprays." An incorrect serving size could lead a consumer to overconsume the product.
5. Your Ultimate Lyme Support Extra Strength, ACJ Joint Extra Strength, ACG Gluco Extra Strength, ACC Cardio Extra Strength, ACN Neuro Extra Strength, ACM Metabo Extra Strength, ACP Prostate Extra Strength, Allergy Care Extra Strength, MRSA Care Extra Strength, Pure Energy Extra Strength, ACP Pulmo Extra Strength, FEM Care Extra Strength and Rash Care Extra Strength products are misbranded within the meaning of section 403(s)(2)(C) of the Act [21 U.S.C. § 343(s)(2)(C)] because the labels fail to identify the part of the plant (e.g., root, leaves) from which each botanical dietary ingredient in the products are derived, as required by 21 CFR 101.4(h)(1).

This letter is not an all-inclusive statement of violations associated with your products or their labeling, and we have not attempted to list here all of the products that are promoted on your website for intended uses that cause them to be drugs. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling for your products to ensure that the claims you make for your products do not reflect intended uses that cause the distribution of the products to violate the Act.

We have reviewed your written responses received August-October 2017, submitted in response to the FDA Form 483, Inspectional Observations, issued to you at the close of the inspection. In general, we have no objections concerning your proposed corrective actions. You must adequately implement and maintain each corrective action to ensure its effectiveness. Your corrective actions will be assessed during a future inspection. This acknowledgement is not intended as an endorsement of current operating conditions within your firm.

We request that you take prompt action to correct all violations associated with your products, including the violations identified in this letter. If you do not believe your products are in violation of the Act, include your reasoning and any supporting information for our consideration. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If the corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which the corrections will be implemented. If you need additional information or have questions, please contact the FDA. You may respond in writing to Hanna L. Potter, Compliance Officer, U.S. Food and Drug Administration, Sixth Avenue and Kipling Street, Building 20 DFC, P.O. Box 25087, Denver, CO 80255-0087. If you have any questions about the contents of this letter, please contact CO Potter at hanna.potter@fda.hhs.gov or 303-236-3094.

Sincerely,

/S/

LaTonya M. Mitchell  
Denver District Director  
Program Division Director  
Office of Human and Animal Food –  
Division IV West

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