**U.S. Food and Drug Administration**
Protecting and Promoting *Your* Health

# Jansen Enterprises, LLC dba HealthWorksUSA 11/24/14

**Department of Health and Human Services**

Public Health Service
Food and Drug Administration
Minneapolis District Office
Central Region
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

November 24, 2014

**WARNING LETTER**

**Via UPS Overnight Delivery**

**Refer to MIN 15 - 02**

Dale L. Jansen
President
Jansen Enterprises, LLC
dba HealthWorksUSA
4233 Wilson Street
Minnetonka, Minnesota 55345-2850

Dear Mr. Jansen:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address *www.healthworksusa.net* in November 2014 and has determined that you take orders there for the products "Nutra Blast Natural Energy," "Ionic Silver Water," "Nutra Complete," and "Nutra Gel," which the website promotes for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1). The therapeutic claims on your website establish that these products are drugs 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 claims found on your website, *www.healthworksusa.net*, that provide evidence that your products are intended for use as drugs include:

**On the cover of your corporate health manual:**

- "Heal yourself of any disease"

**Nutra Blast Natural Energy**

- "[I]ncluding pain relief and joint support."

**Ionic Silver Water**

- "When confronting an illness, take a capful every hour and "swish" it in your mouth for 30 seconds, then swallow it and don't rinse."

**Nutra Complete**

*On the "FAQ" webpage:*

- "It provides the acemannan so your enzymes can make the glycoproteins your cells need to communicate with the macrophages to kill the cancer cells (See: Autoimmune Diseases section)."

**Nutra Gel with Emu Oil**

- "Helps relieve insect bites and other skin problems"
- "Cuts and scratches love the feel of our healing gel"

- “Natural NutraGel helps prevent and heal inflammation due to sun exposure”
- “Now children and fair-skinned people can safely avoid burning!”
- “NutraGel allows you to enjoy the sun longer without damaging your skin.”
- “Helps relieve joint and muscle pain!”
- “Childhood injury visibly improved after only 5 months of applying the gel twice daily” (with a picture of a scarred arm with the scar diminishing).
- “Takes the sting out of bug bites!”

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, these 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 the FDA, as described in section 505(a) of the Act, 21 U.S.C. § 355(a); see also section 301(d) of the Act, 21 U.S.C. § 331(d). FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Furthermore, your Nutra Complete product is offered for a condition that is not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for its intended purposes. Thus, this drug is misbranded within the meaning of section 502(f)(1) of the Act, in that its labeling fails to bear adequate directions for use, 21 U.S.C. § 352(f)(1). The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the Act, 21 U.S.C. § 331(a).

The above violations are not meant to be an all-inclusive list of violations in your products or their labeling. It is your responsibility to ensure that all of your products and labeling are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing within 15 working days from your receipt of this letter of the specific steps you have taken to correct the violations noted above to assure that similar violations do not occur in the future. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for the delay and the date by which each such item will be corrected.

Your reply should be sent to the attention of Compliance Officer Brian D. Garthwaite, Ph.D., at the address on the letterhead.

Sincerely,
/S/
Michael Dutcher, DVM
Director
Minneapolis District