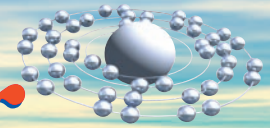




Newsletter



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Dietary Supplements - Regulatory update

FDA: Silver Compounds Cause Argyria

FDA Consumer Advisory Regarding Dietary Supplements

On October 6, 2009, the FDA released a letter to health care professionals warning them about dietary supplements containing silver. The alert was designed to raise awareness regarding the accumulation of excess silver in the skin, resulting in a benign cosmetic condition known as argyria:

“The Food and Drug Administration (FDA) would like to bring to your attention a recently-issued FDA Consumer Advisory about the risk of argyria associated with the use of dietary supplements that contain *silver compounds*, such as colloidal silver...”

The advisory acknowledges that the real concern with silver ingestion comes from silver compounds, not isolated silver particles. Unfortunately, many manufactured colloidal silvers purposefully or inadvertently contain particles neutralized by compounding them with other elements, as with salts or proteins. Unlike the compound-containing colloidal silvers referenced in the advisory, silver hydrosol contains only positive charged silver particles ($Ag_{(n)}^{1+}$) suspended in a pharmaceutical grade purified water, preserving the functionally active form, and do not contain the forms of silver causing concern to medical and regulatory authorities.

If you are concerned about safety, it is nice to know that even Sovereign Silver’s power dosing schedule (7 tsp daily) remains below 350mcg/day, which is the safe oral daily reference dose (RfD) acknowledged by the EPA (and the FDA in its recent advisory).¹

What causes argyria (bluing of the skin)? Peer reviewed published literature on the subject identifies silver compounds (silver salts and proteins) as its cause,^{2,3,4} not isolated nanoscalar and picoscalar silver particles. Why avoid

“Liberty is to the collective body what health is to every individual body. Without health, no pleasure can be tasted by man; without liberty, no happiness can be enjoyed by society.” ---Thomas Jefferson

Communicating the Natural Medicine Message

Q: How are you able to label so clearly the indications for use of the Sovereign Silver® First Aid Gel but not the silver hydrosol?

A: Homeopathic medicine is regulated as a drug by the FDA, according to the Homeopathic Pharmacopoeia of the United States (HPUS). Therefore, every over-the-counter homeopathic product must have clear indications for its active ingredient(s), as supported by authoritative Materia Medica. Sovereign Silver® First Aid Gel carries clear indications for its Argentum metallicum (homeopathic silver). Our silver hydrosols are regulated as dietary supplements and, therefore, cannot make any drug claims.



SILVER CONCENTRATION	RfD 1 teaspoon taken once a day	RfD Power dose: 1 teaspoon taken 5-7 times daily
10 ppm	50 mcg	250-350 mcg
25 ppm	125 mcg	625-878 mcg
50 ppm	250 mcg	1,250-1750 mcg
100 ppm	500 mcg	2,500-3,500 mcg
250 ppm	1,250 mcg	6,250-8,750 mcg
500 ppm	2,500 mcg	12,500-17,500 mcg
1,000 ppm	5,000 mcg	25,000-35,000 mcg
2,000 ppm	10,000 mcg	50,000-70,000 mcg

Relative Toxicity by General Species of Silver

Highest	↑	Salt solution - inorganic
		Salt solution - organic
		Salt alkali
		Protein complex / crystaloid Oxide
		Colloidal dispersion
		Hydrosol
		Homeopathic
Lowest	↓	

high-PPM concentrations? High PPM colloidal silvers are primarily protein or salt compounds.⁵ More is definitely not better. Less can be more. Unlike colloidal silver, a bioactive silver hydrosol has a safety profile more like a homeopathic remedy!

¹US Environmental Protection Agency. Silver CASRN 7440-22-4: Reference dose for chronic oral exposure (RfD). Washington, DC 1991.

²Brandt D, Park B, Hoang M, Jacobe HT. Argyria secondary to ingestion of homemade silver solution. Journal of the American Academy of Dermatology 2005;53(2)1:105-107.

³Stilians AW. Argyria. Archives of Dermatology and Syphilology 1937;35:67-77.

⁴Becker SW, Ritchie EB. Argyria following excessive use of silver arsphenamine. JAMA 1931;97:389-390.

⁵Hill WR, Pillsbury DM. Proprietary Silver Compounds. In: Argyria: The Pharmacology of Silver. Baltimore, MD: The Williams & Wilkins Co., 1939:169-172.

Each batch of Sovereign Silver® undergoes the most stringent Quality Control and Quality Assurance testing, including third party laboratory confirmation.

Our Total Quality Assurance approach to manufacturing requires continuous testing during all the steps of production.

QA TEST PROCEDURE LEVEL DONE

QA TEST PROCEDURE	LEVEL	DONE
Microbial load batch testing	No growth	
Fungal & bacterial species sterile	No growth	
Organochlorine pesticides	0	
Organophosphorous pesticides	0	
Carbamates pesticides	0	
Heavy metals (As, Cd, Cr, Pb)	0	
Heavy metal (Hg)	0	
Pyrogens / endotoxins levels	0	
TEM microscopy performed	100,000x	
Organoleptic	Passed	
Product concentration (PPM)	10 PPM	
Standardization (pH, conductivity)	Passed	

Legislative Update - Health Freedom

Senate Hearing Examines DSHEA vs. Pre-market Approval

Those who care for their health with dietary supplements cherish their freedom to access natural healing therapies and substances. As it has always been, the price of liberty is eternal vigilance.

There may be a new effort afoot to restrict access to dietary supplements, originating in the Senate from concerns over supplements adulterated with trace amounts of anabolic steroids.

The Senate Judiciary's Subcommittee on Crime and Drugs held a hearing, presided over by subcommittee chairman Senator Arlen Specter (D-PA) and ranking member Senator Orrin Hatch (R-UT), concerning hidden steroids in bodybuilding products. Based upon these adulterated supplements, Sen. Specter trial-ballooned the idea that supplements should be pre-approved at the federal level before being allowed to be sold. This would effectively make new dietary food supplements illegal unless first receiving authorization from the FDA.

Since the Dietary Supplement Health & Education Act of 1994 (DSHEA), dietary supplements have been protected from excessive regulation and pre-market approval. DSHEA was made possible only because of a millions-strong groundswell of natural health consumers were concerned that the federal bureaucracy would treat their food supplements as drugs. If this were to happen, most dietary

MYTHS:

Myth: The higher the PPM the more effective the product.

Fact: What makes one silver product more beneficial than another is not its PPM but rather its particle size and particle charge & Zeta potential, which allows the active silver particles to remain in stable suspension¹ for use by the body. The smaller the particle, the more bio-available it becomes, and the greater surface area is available for interaction within the body.*

*This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.

¹Rentz EJ. Viral Pathogens and Severe Acute Respiratory Syndrome: Oligodynamic Ag+ for Direct Immune Intervention. Journal of Nutritional and Environmental Medicine 2003;13(2):109-118.

Testimonial Corner:

“Satisfaction at every turn.”

“I cannot possibly tell you how completely satisfied I am with your product, and your company!! I have been using your product for several years, with NO problems whatsoever, and now that I have had to order direct from you, I waited, what? 2 Business days for delivery? I'm still in shock, but feeling all the more healthy for it!! God Bless All of You, and Thank You So Much for returning my health in such a short turn-around time!!” -- AJ Corbett, Florida

supplement manufacturers would not have the resources to bring new products to market, resulting in much less innovation and higher prices on existing products.

Industry supporters maintain that the problem lies with lack of FDA enforcement of existing regulations and not the lack of new regulations.

Natural Products industry attorney Marc Ullman believes that DSHEA is in jeopardy. “Not only because I think that this issue will not go away, but because I am concerned that overall lack of enforcement by FDA has created an atmosphere where frauds/charlatans feel that there is next to no risk in entering the supplement field and selling their illegal products,” he said.

Many congressional representatives do not understand this issue thoroughly and wrongly attack DSHEA, rather than recognizing the FDA's inefficiency at enforcing current guidelines. Let your congressional representative know that we do not need additional restrictions on dietary supplements, just better enforcement of the provisions within DSHEA. Call your Congressional Representative TODAY at **1-866-220-0044**.

Please also see the Sept-Oct issue of the Sovereign Silver Newsletter to learn more about the health freedom legislation currently under consideration: HR 3394, 3395 and 3396.

