

sci.med.diseases.lyme: Re: Time to admit silver works folks.

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From: A_Weisman (a_weisman_at_yahoo.com)

Date: 12/04/04

Date: 4 Dec 2004 07:21:56 -0800

dali <weeble@wabble.com> wrote in message news:<bqf2r0tff7tnbnjg17o2vhtr1vrh7etet4@4ax.com>...

> On 04 Dec 2004 01:56:45 GMT, chuckpadams04@aol.com (ChuckPAdams04)

> wrote:

>

> >Troll.

> >

> >ABUSE REPORT SENT YOU SILVER FRAUD.

> >

> >

> >CPA

>

> Call the FDA to Oh wait they agree silver does work

Absolute utter freaking bullshit.

Bad enough you silver freaks come here to proselytize about the silver (which ALL of you sell too).

But to utterly blatantly say something so completely false and misleading, well the silver must have rotted away whatever brain you ever had.

Yeah silver works. To cause agryia and other health problems.

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The following is shortened, highlighting the important stuff. Edited places will be marked with a [...].

Federal Register: August 17, 1999 (Volume 64, Number 158)]

[Rules and Regulations][Page 44653-44658]

>From the Federal Register Online via GPO Access [wais.access.gpo.gov]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration
21 CFR Part 310[Docket No. 96N-0144]

Re: Time to admit silver works folks.

Over-the-Counter Drug Products Containing Colloidal Silver
Ingredients or Silver Salts AGENCY: Food and Drug Administration, HHS.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing that all over-the-counter (OTC) drug products containing colloidal silver ingredients or silver salts for internal or external use are NOT GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND ARE MISBRANDED. FDA is issuing this final rule because many OTC drug products containing colloidal silver ingredients or silver salts are being marketed for numerous serious disease conditions and FDA is NOT AWARE OF ANY SUBSTANTIAL SCIENTIFIC EVIDENCE THAT SUPPORTS THE USE OF OTC COLLOIDAL SILVER INGREDIENTS or silver salts for these disease conditions.

DATES: This regulation is effective September 16, 1999.
FOR FURTHER INFORMATION CONTACT: Bradford W. Williams, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-0063. SUPPLEMENTARY INFORMATION:

I. Background ... declare that all OTC drug products containing colloidal silver ingredients or silver salts are NOT GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE, and are new drugs and misbranded within the meaning of section Colloidal silver is a suspension of silver particles in a colloidal base. In recent years, colloidal silver preparations of unknown formulation have been appearing in retail outlets. These products are labeled for numerous disease conditions, many of which are serious diseases. The dosage form of these colloidal silver products is usually oral, but product labeling also contains directions for topical and, occasionally, intravenous use.

FDA has NOT APPROVED A NEW DRUG APPLICATION (NDA) for any colloidal silver product. NONE of the silver salts evaluated as part of FDA's OTC drug review WAS FOUND TO BE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE for its intended use(s). FDA is NOT AWARE OF ANY SUBSTANTIAL SCIENTIFIC EVIDENCE THAT SUPPORTS THE USE OF OTC COLLOIDAL SILVER INGREDIENTS OR SILVER SALTS FOR

DISEASE CONDITIONS. The agency invited any interested parties to collect and submit any existing data and information that support the safety and effectiveness of colloidal silver ingredients or silver salts for any of the uses not already evaluated under the OTC drug review. Interested persons were invited to submit written comments on the proposed regulation and on the agency's economic impact determination by January 13, 1997.

...
Based on the information set forth in the proposed rule, and after consideration of the information submitted by the public comments (as summarized as follows), FDA is declaring that all OTC drug products containing colloidal silver ingredients or silver salts are not generally recognized as safe and effective, and are new drugs and misbranded within the meaning of section 201(p) of the act. Adequate safety and effectiveness data have not been provided to establish general recognition of the safety and effectiveness of colloidal silver or silver salt ingredients for any OTC drug uses. The data submitted did not include the required absorption, metabolism, tissue distribution, accumulation, excretion, and pharmacodynamics (effect of the drug at its action site) of silver in the body, both when taken internally and applied externally, and of the effect of the particle size of the silver on these systemic effects.

FDA is amending subpart E of part 310 (21 CFR part 310) to add Sec. 310.548 for OTC drug products containing colloidal silver ingredients or silver salts. The agency has expanded proposed Sec. 310.548(a) to include some additional silver ingredients.

II. Public Comments and the Agency's Response

A. General Comments

1. Many comments agreed with the proposed rule. One of these comments cautioned against the DANGERS of using untested drugs and recalled that Laetrile MISLED UNSUSPECTING PEOPLE IN SEARCH OF A QUICK CURE. Another comment provided personal experience as a victim of argyria who had been DISFIGURED for 40 years as a result of using colloidal silver. This comment included an excerpt from a book that recorded 114 cases of argyria compiled in the 1930's. The comment contended that many marketers of colloidal silver deny the POTENTIAL FOR HARM and often MISQUOTE OR DISTORT THE HISTORICAL ARTICLES DEALING WITH THESE PRODUCTS.

A physician, who was formerly a pharmacist, recounted his own experience in reviewing cases of argyria. The victims had ingested silver products in the 1940's and 1950's. The physician was concerned that a product that does not have any rational use would lead to the redevelopment of argyria as a clinical problem. Another physician/ophthalmologist commented that colloidal silver is DANGEROUS QUACKERY.

The agency appreciates these comments in support of its proposal.

B. Comments on Safety and Effectiveness

2. One comment expressed concern that many different silver products being marketed are inferior products and are not even true colloids. Another comment stated that the vast majority of silver products being sold are **FRADULENT PRODUCTS**. The comment noted that it had tested a number of these products and found that several actually had no silver content, one did not contain the silver particle size as stated on the label, and only one product exceeded all stated purity and stability claims found on the label. The comment added that many of the products were only duplicates of older colloidal silver products. The comment considered these "newer" products as having the same dangers, intermittent effectiveness, and lack of stability as the older products. The comment contended that the vast majority of the colloidal silver products it tested are **TOTALLY USELESS**, some were **DANGEROUS** to ingest, and some were possibly a **THREAT TO LIFE**. The comment stated that it is a major problem to keep off the market these so-called "colloidal silver" products that contain significant amounts of silver ions and silver salts. ...

...

3. Several comments submitted information purporting to support the safety of colloidal silver and other silver ingredients. The comments contended that silver is nontoxic and has minimal side effects.,.... Several comments mentioned that argyria, a blue skin discoloration resulting from prolonged administration of silver compounds and accumulation in the body, is the main side effect that occurs. ... The comment concluded that the dilute, mild silver protein products marketed today are similar to pre-1938 colloidal silver solutions and do not cause argyria. ...

Another comment presented the results of several animal (rat) studies involving acute or chronic administration of various amounts of colloidal silver (mild silver protein in colloidal suspension), approximately 1,500 parts per million (ppm), either by intravenous (IV) injection or in drinking water. ...The investigator reported that no abnormal clinical or behavioral signs were observed after 12 days of treatment. In another followup chronic IV rat study, three rats were injected with 1,500 ppm colloidal silver three times per week for 4 weeks (a total of 18 mg per 300 gram (g) rat), and three rats served as controls. ... there were no differences in body weight and no clinical

signs or gross pathologic changes between the treated and control groups....The rats showed no clinical signs of gross pathological changes at the end of the treatment period. Three rats received regular drinking water and served as controls. The investigator stated that the data do not provide information about the metabolic fate of the silver, but support safety if extrapolated to humans because a 60–kg person would have to be given 3,600 mg to receive an amount equivalent to the rats' highest dose (18 mg/300 g rat).

The agency does not consider this information adequate to establish general recognition of the safety of silver salts or colloidal silver ingredients for OTC drug use. THE COMMENTS THEMSELVES INDICATE THAT IONIC SILVER SALTS AND HIGHLY CONCENTRATED MILD SILVER PROTEIN CLEARLY ARE NOT SAFE FOR for OTC use. The animal data indicate that mild silver protein in colloidal suspension at low concentrations may be safe in rats when administered in specific concentrations for up to 40 days. Additional data are needed in humans on the absorption, metabolism, tissue distribution, accumulation, excretion, and pharmacodynamics of silver in the body, both when taken internally and applied externally, and of the effect of the particle size of the silver on these systemic effects. The agency concludes that a full pharmacologic profile that is relevant to human use is needed.

4. Several comments submitted information purporting to support the effectiveness of colloidal silver and other silver ingredients. One comment provided a partial list of the more than 650 diseases that colloidal silver has been used against and included a number of testimonials. Another comment stated that silver will kill 650 disease organisms, but it DOES NOT CURE 650 DISEASES. ... Another comment noted the antimicrobial and bacteriostatic effects of diluted colloidal silver protein solutions. ...

Another comment, from a physician, described a double–blind clinical study that he conducted using a commercial colloidal silver product.... ...The men reported that nocturia (frequency of urination) ranged from one to five times a night. The physician assumed that the men had benign prostatic hypertrophy because of their age and the onset of symptoms in recent years. Of the 22 men, 15 took colloidal silver and 7 took placebo (colored water). ...At the end of the study, four men (all on the colloidal silver) reported considerable improvement in the nocturia, with a reduction from 2 to 4 times to 1 time each night, while six other men (five on the colloidal silver) noted some improvement in the nocturia. TWO MEN WITH A HISTORY OF TRANSURETHRAL RESECTION OF THE PROSTATE, WHO WERE ON THE COLLOIDAL SILVER, DID NOT REPORT ANY

IMPROVEMENT.

...The physician concluded that the results of this study merit further investigation by the medical community.

The agency finds that the previous studies are not adequate and well-controlled clinical studies of the type described in Sec.... that need to be conducted. The studies have major methodic flaws. There needs to be a clear statement of the objectives of the investigation and a protocol containing a specific study design, the method of subject selection (with inclusion and exclusion criteria), the method of assigning subjects to treatment and control groups, well-defined methods for measuring the subjects' responses, and methods for analysis of the study results. Adequate measures need to be taken to minimize bias on the part of the subjects, observers, and analysts of the data, which is done by adequate blinding. The agency is unable to determine the adequacy of the blinding in the physician's study because the placebo was described as "colored water." The agency is not able to ascertain the degree of similarity or difference that existed in the appearance of the colloidal silver product and the placebo to determine how well the study was blinded. ... Likewise, the conditions described in the case reports provided by one comment need to be studied in adequate and well-controlled clinical trials. Finally, the information that silver will kill 650 disease organisms and that a Bredig Sol of silver at 30 ppm is an effective germicide for both gram-positive and gram-negative bacteria, fungi, yeasts, and viruses needs to be related to in vivo treatment for specific disease conditions. The agency concludes that the data and information submitted are not sufficient to establish general recognition of effectiveness for colloidal silver or other silver ingredients for any specific OTC condition....

... None of the comments provided any evidence to show that the composition and the labeling of colloidal silver or silver salt drug products have remained unchanged since 1938 or 1962. Without such evidence, the products cannot qualify for either grandfather exemption, and there is no need to set any guidelines as requested by one comment.

D. Freedom of Choice
6. A number of comments included individual testimonials or expressions of belief that colloidal silver benefited their health and that of their family members or friends. A few comments mentioned benefits experienced by pets. Many of the comments stated that the proposed rule would deny them the freedom of choice to select their own drugs.

FDA's statutory mandate includes protection and promotion of the public health by ensuring that drugs are not only safe but also effective for their intended use. The Commissioner of Food and Drugs'

decision on the status of Laetrile, published in the Federal Register of August 5, 1977 (42 FR 39788), expresses the agency's position on freedom of choice with respect to ensuring that drugs are not only safe, but also effective. That statement reads in part:

In passing the 1962 Amendments to the act—the amendments that require that a drug be proved effective before it may be marketed—Congress indicated its conclusions that the absolute freedom to choose an ineffective drug was properly surrendered in exchange for the freedom from the danger to each person's health and well-being from the sale and use of WORTHLESS DRUGS * * *. To the extent that any freedom

[[Page 44657]]has been surrendered by the passage of the legislation which bans

from the marketplace drugs that have not been proven to be effective, that surrender was a rational decision which has resulted in the achievement of a greater freedom from the dangers to health and welfare represented by such drugs.

Agency regulations in 21 CFR 330.10(a)(4)(ii) state that the standards for effectiveness for an OTC drug that is generally recognized as effective include a requirement for controlled clinical investigations. Isolated case reports, random experience, and reports lacking the details that permit scientific evaluation are not considered adequate to establish effectiveness. Testimonials from consumers cannot be considered as adequate proof of effectiveness or safety. None of the comments presented any evidence of safety or effectiveness beyond personal experience.

In the absence of data demonstrating that the ingredients present in OTC drug products containing colloidal silver ingredients or silver salts are generally recognized as safe and effective, these ingredients cannot be included in an OTC drug product. After the effective date of the final regulation, any such OTC drug product initially introduced or

initially delivered for introduction into interstate commerce (unless it is the subject of an approved NDA, of which there currently are none) that is not in compliance with this regulation will be subject to regulatory action. E. The Dietary Supplement Health and Education Act (DSHEA)

7. Several comments, from consumers, stated that the specific product they used did not make any claims and might be considered a dietary supplement. None of the comments provided any labeling or specifics about the products they used.

This final rule addresses products marketed as OTC drugs. A product that is not intended for OTC "drug" use in accord with section 201(g)(1) of the act would not be subject to this final rule. A product containing silver could, under certain circumstances, be marketed as a dietary supplement if it meets the definition in section 201(ff) of the

act and other applicable requirements. Among other things, such a product's label must state that the product is a dietary supplement and meet other labeling requirements of the act. (See, e.g., section 403(q), (r), and (s) of the act (21 U.S.C. 343(q), (r), and (s)).) It must also meet the safety requirements of the act. (See, e.g., 21 U.S.C. 342(a), (f), and (g).) FDA may take regulatory action against a product marketed as a dietary supplement when authorized to do so by the act.

A dietary supplement containing colloidal silver or silver salts may not be labeled in whole or in part for topical use. Section 201(ff)(2)(A)(i) of the act requires that a dietary supplement is a product that is "intended for ingestion." The term ingestion has been addressed by the court in *United States v. Ten Cartons, Ener-B Nasal Gel*, 888 F. Supp. 393 (E.D.N.Y.), *aff'd*, 72 F.3d 285 (2d Cir. 1995). A topical product could not be a dietary supplement.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities.

Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.) requires that agencies prepare a written statement and economic analysis before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation). As the agency stated in the proposed rule, this rulemaking is not expected to pose a significant impact on small business because only a limited number of products are affected (61 FR 53685 at 53687).

The agency believes that this final rule is consistent with the principles set out in the Executive Order and in these two statutes. The purpose of this final rule is to establish that all OTC drug products containing colloidal silver ingredients or silver salts for internal or external use are not generally recognized as safe and effective and are misbranded. The agency's Drug Listing System identifies a multitude of silver-containing products. These products may contain silver, silver ion, silver chloride, silver cyanide, silver iodide, silver oxide, or silver phosphate.

All of these manufacturers are considered small entities, using the U.S. Small Business Administration designation for this industry (750employees).

Manufacturers will no longer be able to market OTC drug products containing any silver ingredients after the effective date of the final rule. While the manufacturers may incur a loss of revenue from some of these products, some silver products for internal use may be able to continue to be marketed as dietary supplements, provided they meet, among other regulatory requirements applicable to dietary supplements, the definition of dietary supplements in section 201(ff) of the act and meet the labeling requirements of section 403 of the act.

Manufacturers have been aware of the possible effects on the status of these OTC silver drug products since October 1996 and have not submitted adequate safety and effectiveness data to the agency. Since publication of the 1996 proposal and with the 30-day implementation date after publication of the final rule, manufacturers should have ample time to deplete most of their remaining stock of OTC drug products containing the affected ingredients.

There is more – to read the entire article, go to :

<http://www.fda.gov/OHRMS/DOCKETS/98fr/081799a.txt>

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Between October 1993 and September 1994, the FDA issued warning letters to five colloidal silver marketers::

* Higher Education Library Publications (H.E.L.P.), of Springfield, Utah, was ordered to stop claiming that its colloidal silver product was effective as a natural antibiotic and might be effective against cancer, genito-urinary diseases, tuberculosis, and AIDS.

* Nutrition, Inc., of Arvada, Colorado, was ordered to stop stating or implying that its Silvicidal, when administered orally or intravenously, was nontoxic, FDA-approved, and was a broad-spectrum antibiotic that killed bacteria and all virus and fungal infections. In addition, it was falsely claimed to be effective against a long list of specific diseases.

* Reseau International of Cincinnati, Ohio was ordered to stop claiming

that its colloidal silver product was a "natural antibiotic and anti-inflammatory immune system stimulant" and that it was effective against cancer, staph, strep, influenza, general body infections, inflammation, impaired immune system, fungus toxicity, tonsillitis, Meniere's symptoms, whooping cough, shingles, syphilis, cholera, and malaria. The labeling also stated that colloidal silver could cause major growth stimulation of human tissues and can regenerate

* Silverado Inc., of Bountiful, Utah, was warned to stop making false claims that its colloidal silver product was effective as an antibiotic, anti-inflammatory, anti-viral, and anti-fungal agent and that it could stimulate the immune system.

* Unic, of Carmichael, California, was ordered to stop claiming that its colloidal silver product was effective against many diseases and could heal burn-damaged tissue without scarring.

In October 1996, the FDA proposed to ban the use of colloidal silver or silver salts in over-the-counter products [7]. A Final Rule banning such use was issued on August 17, 1999 and became effective September 16th. The rule applies to any nonprescription colloidal silver or silver salt product claimed to be effective in preventing or treating any disease [8]. Silver products can still be sold as "dietary supplements" provided that no health claims are made for them. During 2000, the FDA issued warnings to more than 20 companies whose Web sites were making illegal therapeutic claims for colloidal silver products.

In 2000, the Federal Court of Australia banned Vital Earth Company Pty Limited and its director Darryl John Jones from falsely representing that the colloidal silver produced by their "Vital Silver 3000 Zapper," "Vital Silver 2000 Automatic" and "Vital Silver 2000":

* Can kill all disease-causing bacteria, fungi and virus within six minutes

of contact

* Has no harmful side effects; that colloidal silver could be used as an

antibiotic for all the acquired diseases of active AIDS

* Is effective with more than 650 different pathogenic bacteria and virus types

* Has been used successfully against diseases including AIDS, cholera, diabetes, leprosy, leukemia, lupus, skin cancer, syphilis and whooping cough.

The company was also ordered to pay AUS\$9000 in costs and to provide refunds [9].

In 2001, the FTC obtained consent agreements with two companies:

* Robert C. Spencer and Lisa M. Spencer, doing business as Aaron Company (Palm Bay, Florida). Colloidal silver has been medically proven to kill over 650 disease-causing organisms in the body and is effective in curing diseases ranging from cancer and multiple sclerosis to HIV/AIDS [10].

* ForMor, Inc., doing business as ForMor International, and its president, Stan Gross (Birmingham, Alabama) agreed not to make unsubstantiated claims that colloidal silver is effective in treating over 650 infectious diseases, has no adverse side effects, and is effective against arthritis, blood poisoning, cancer, cholera, diphtheria, diabetes, dysentery, gonorrhea, herpes, influenza, leprosy, lupus, malaria, meningitis, rheumatism, shingles, staph infections, strep infections, syphilis, tuberculosis, whooping cough, and yeast infections [10].

In 2002, the FTC obtained a consent agreement with Kris Pletschke, doing business as Raw Health, agreed to stop making unsubstantiated claims that its colloidal silver product could treat or cure 650 different diseases; eliminate all pathogens in the human body in six minutes or less; and is medically proven to kill every destructive bacterial, viral, and fungal organism in the body,

including anthrax, Ebola, Hanta, and flesh-eating bacteria [12].

In 2002, the Australian Therapeutic Goods Administration amended its rules so that water-treatment products containing substances like colloidal silver for which therapeutic claims are made must meet the requirements of medicines included in the Australian Register of Therapeutic Goods. This means that such products can no longer be legally marketed without proof that they are safe and effective for their intended purpose. The amendment was based on conclusions that:

- * There is little evidence to support therapeutic claims made for colloidal silver products;
- * The risk to consumers of silver toxicity outweighs the value of trying an unsubstantiated treatment, and bacterial resistance to silver can occur
- * Efforts should be made to curb the illegal availability of colloidal silver products, which is a significant public health issue [11] .

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FDA
TALK PAPER
Food and Drug Administration
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, MD 20857

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T99-39 Print Media: 301-827-6242
August 17, 1999 Broadcast Media: 301-827-3434

Consumer Inquiries: 888-INFO-FDA

FDA ISSUES FINAL RULE ON
OTC DRUG PRODUCTS CONTAINING COLLOIDAL SILVER>
The FDA has issued a Final Rule declaring that all over-the-counter (OTC) drug products containing colloidal silver or silver salts are not recognized as safe and effective and are misbranded. Colloidal silver is a suspension of silver particles in a colloidal (gelatinous) base. In recent years, colloidal silver preparations of unknown formulation have been appearing in stores. These products are labeled to treat adults and children for diseases including HIV, AIDS, cancer, tuberculosis, malaria, lupus, syphilis, scarlet fever, shingles, herpes, pneumonia, typhoid, tetanus and many others.

According to the Final Rule, a colloidal silver product for any drug use will first have to be approved by FDA under the new drug application procedures. The Final rule classifies colloidal silver products as misbranded because adequate directions cannot be written so that the general public can use these drugs safely for their intended purposes. They are also misbranded when their labeling falsely suggests that there is substantial scientific evidence to establish that the drugs are safe and effective for their intended uses.

The indiscriminate use of colloidal silver solutions has resulted in cases of argyria, a permanent blue-gray discoloration of the skin and deep tissues.

Colloidal silver ingredients and silver salts include silver proteins, mild silver protein, strong silver protein, silver chloride, and silver iodide. The dosage form of these colloidal silver products is usually oral, but product labeling also contains directions for topical and, occasionally, intravenous use.

In reaching its decision, FDA considered all of the information described in the proposed rule (October 15, 1996) and submitted by the public in response to that proposal, the Final Rule becomes effective on September 16, 1999, 30 days after publication.

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- > *Silvadene – Marion Laboratories: FDA Approved Silver Sulfadiazine Cream*
 - > *Silvadene is an FDA approved topical cream used in over 70% of hospitals in the United States to prevent bacterial infections at burn sites, improve tissue healing, reduce scarring, and is often prescribed as a topical treatment for skin graft donor sites. This silver-rich cream (a chemically produced silver salt compound) is FDA approved as a topical antifungal and antibacterial for external use, and available on with a prescription. Silvadene has been proven effective against both gram-positive and gram-negative bacteria, including resistant strains.*
 - >
 - > *I could print these silver products all day long. I guess all these doctors using silver are quacks huh? sure. history is already being made and the use of silver will continue. period.*
 - >
 - >
 - > *IMO silver should be used with traditional abx for serious infections.*
 - > *Hit the bacteria in as many ways as possible.*