

Evaluating Nutraceuticals and Supplements

MEDICAL FAQs

INTRODUCTION

The term "nutraceutical" was invented by Dr Stephen DeFelice, and defined as "...a food or a part of a food that provides medical or health benefits...." In veterinary medicine, nutraceuticals are generally defined as being "endogenous substances", and exclude foods or botanicals.

Nutraceuticals and dietary supplements are commonly used in veterinary and human medicine. They are either specifically defined by the FDA or not defined (and not regulated). However, any compound that claims on the packaging label to have benefit in treating disease can be classified (and regulated) as a drug (although the FDA may choose to ignore such breaches if the product does not appear to harm humans).

CLINICAL USE INFORMATION

How do I evaluate the quality of a nutraceutical?

Since there is no regulatory body for manufacturing of nutraceuticals, it becomes difficult to assess product quality. Drugs, regulated by the FDA must meet specific manufacturing standards. Studies have shown that nutraceuticals are commonly mislabeled; may contain impurities, such as heavy metals, toxins, bacteria, molds; may have variable quantities of active ingredients; may fail to dissolve (thereby remaining ineffective).

Some guidelines for selecting products **likely to be** of better quality include:

1. Price. Cheaper compounds are less likely to be of high quality. This has been the general observation with chondroitin sulfate.
2. Lot number and Expiration Date.
3. Monograph within the US Pharmacopeia, documenting accuracy of ingredient labeling. There is a general [USP veterinary page](#) (for veterinary drugs, requires free registration) and the [USP Dietary Supplement Verification Program](#) page, which provides a list of suppliers that have voluntarily submitted their products for USP verification and approval. However, this does not mean that products not verified by USP DSVP are of poor quality.

USP-verified
Dietary
Supplements
carry a mark
on the label.



An alternative is that certain ingredients are USP-verified (these carry a different mark)



4. Claims of safety or efficacy. If a nutraceutical claims a medical benefit on the label, there should be a New Animal Drug Application (NADA) number accompanying the product. While this is "mandated" by law, it is often ignored. A NADA tends to suggest higher quality, because the manufacturer has bothered to abide by FDA regulations for drug manufacture.
5. Ingredient list. All ingredients should be listed by order of magnitude based on weight.
6. Good instructions for use.
7. Scientific evidence supporting manufacturer's claims. Some manufacturers have begun providing data for their specific products through independent scientific studies. These studies

should ideally be peer-reviewed and published. Importantly, they should be **clinical studies**, not *in vitro* studies. There are institutes, affiliated with universities and medical schools, who are beginning to investigate nutraceutical claims scientifically. These include [The Nutraceuticals Institute](#), [The Institute of Nutraceutical Research](#), and others.

8. Testimonials in place of valid research. Many companies provide testimonials from "satisfied clients". These should be ignored, and companies that promote these instead of scientific research supporting their claims, should be viewed skeptically.
9. Membership in National Animal Supplement Council (www.nasc.cc). This industry group has a close relationship with FDA and strict guidelines for member companies regarding quality control and adverse event recording. Member companies are likely to have better quality products.

While querying the manufacturer regards Good Manufacturing Policy is a noble goal, most clinicians would be unable to ask the correct questions or evaluate the answers provided.

How do I evaluate the safety of a nutraceutical?

Safety has 2 components - safety of the active ingredient(s) and risk of contaminants. Good quality products have a lower risk of contaminants. Additionally, they tend to have more consistent quantities of the active ingredient from batch to batch.

Safety of the active ingredients includes knowing the primary source of the ingredients - what substance/tissue they were extracted from. Toxicity of the active ingredients should be evaluated by LD50 studies (if possible). Studies showing hematological or biochemical perturbations should be evaluated if possible.

How do I evaluate the efficacy of a nutraceutical?

Efficacy can also be evaluated, but can be difficult. Manufacturers can be queried about their **specific formulations** (e.g. different calcium salts have markedly different absorptive properties in the GI tract) so if a specific formulation is used, data showing efficacy (e.g. increasing serum [calcium]) as well as potential negative effects, should be available.

The **mechanism of action** by which a nutraceutical affects a disease process should be elucidated. This can be difficult to determine because many of these substances have multiple components that might interact.

Bioavailability of the compound and **measurable presence** of the compound at the targeted site should be evaluated. For example, both glucosamine and chondroitin sulfate have been shown to be taken up by cartilage.

Ultimately, **studies** demonstrating the clinical benefits of a nutraceutical should be evaluated. For example, several peer-reviewed studies exist documenting improvement in clinical signs with chronic osteoarthritis in dogs or horses given glucosamine or chondroitin sulfate (or combinations of these compounds). However, clinicians should examine how the studies were conducted, to determine their likely validity, because many studies are poorly designed or executed. Studies should be placebo-controlled and blinded, if possible. Experimental studies should be examined if possible, where animal models or *in vitro* may provide more objective end-points for assessing efficacy.

Dr Andrea Fascetti of UC Davis provides some useful guidelines that a clinician should ask prior to prescribing a nutraceutical:

1. "Does the product do what it claims to do?" "What studies have been done to prove this, or are testimonials the only proof?"
2. "Does the product contain what it claims it does, and if so, is the product bioavailable?"
3. "If studies have been conducted on the compound, were they in vivo or in vitro?"
4. "Were the studies done in the target species?"

5. "Did the studies employ the same dose as is contained in the product?"
 6. "Were the studies well-controlled?"
 7. "Were the studies published in a peer-reviewed journal or similarly reputable source?"
 8. "What are the active ingredients in products containing multiple substances, and what is the potential they may interact in a negative manner?"
 9. "What other medications is my patient receiving, and how might the nutraceutical in question interact with them?"
 10. "What work has been done to verify the safety at the dosage of intended use?"
 11. "Has a margin of safety (the difference between effective dose and maximum safe dose) been established?"
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What resources are there to help me?

Several websites exist that may help a clinician investigate specific nutraceuticals:

1. www.quackwatch.com
2. www.herbalgram.org
3. <http://nccam.nih.gov>
4. www.navigator.tufts.edu/index.html
5. www.consumerlab.com
6. www.biovalidity.com

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