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Dear FDA policymakers,

I'd like to offer a perspective from my experiences on the internet, and suggest three specific solutions that I feel the FDA should implement immediately.

In 1995, I wrote up the charters for the new global discussion groups on skin diseases. In the four years since then, I've participated and provided information resources for the support groups. The psoriasis support group in particular has become a virtual community of many caring people, including several professionals, who volunteer their time to answer questions and provide emotional support. To give an idea of the popularity, there are about 50,000 messages in the psoriasis group archive alone.

Most of the discussion in our open forum relates to questions about the various treatments available. Perhaps because the group has a no-promotion policy, it has become the main place to find a counterpoint to the product claims made in advertising. To help answer the many repeated questions about advertised miracle cures and products that seem too good to be true, one of the things I've done at my pinch/skin web site is to compile a list of facts about some of the most deceptive and misleading claims. At this page, [titled the Psoriasis Hall of Pshame,] I also list information for consumers about FDA and FTC regulatory guidelines regarding not just dietary supplements and "nutraceuticals", but OTC drug products, topical treatments, medical devices, and even undisclosed secret cures.

What I'd like to offer are some simple proposals that could defuse many of the misleading promotions. These changes could apply not only to dietary supplements, but nearly all products that consumers might choose for improving their health. They are simple, cost effective measures that allow for the industry to be more self-regulating.

The DSHEA was clearly popular because consumers have a need for more information regarding personal health decisions. When making these decisions, we must always weigh the benefits against the risks. The promoters obviously want to concentrate on the benefits, and avoid any mention of possible side effects.

Listing the ingredients on the product label is important for making an ***informed*** decision can be made ***at the point of sale***. In almost any deceptive or misleading mail order promotion, this information is just not available. Even if a phone number is listed, a call to ask about the ingredients usually leads to a sales pitch by someone who is there to take an order, and doesn't have access to the ingredient list. Ads and press releases often address consumer concerns by giving a laundry list of what ***isn't*** in a product, rather than simply revealing the actual ingredients.

1) Product ingredient information needs to be available online.
One of the marvels of hypertext on a web site is that an unobtrusive link can be made to more information. I can think of no legitimate reason why any promotion that lists the details of a specific product prior to sale shouldn't also provide an accurate ingredient list. On a web site, this is a trivial matter that puts no burden on the promoter. For press releases and printed ads, either the ingredients or the inclusion of a web site address providing label information is a must.

Cost to the promoter can hardly be an issue, since free web page providers are everywhere on the net. Many ads *do* provide a web address along with phone, fax, and email contact info, but the web sites often lack ingredient details. For promoters or distributors who don't maintain a web site, the manufacturer or packager should be required to provide an ***online*** product label as part of good manufacturing practice.

This simple requirement, similar to the guidelines for prescription drug broadcast marketing, would provide needed information to consumers and improve self-regulation at the commercial. Internet service providers and print publishers who carry advertising have the ability to decide which ads to carry. They have been cooperative in limiting obvious frauds by establishing acceptable use policies, but they depend on having clear legal guidelines that they can enforce. Deceptive promotions for products that lack ingredient information could be easily addressed by the publisher carrying the content. Even before any need for enforcement, having an online ingredient list could become a standard for weeding out unethical ads.

2) Every product label should carry a *Manufacturer's Statement on Precautions and Side Effects*.
If the claim is "***None***" for a particular product, but comparison shopping shows similar products with fair warnings, it will be clear when the consumer isn't getting the whole story. Making it clearly a claim ***by the manufacturer*** takes the burden and accountability for the statements off the FDA, and puts it back onto the producers where it belongs. An improvement on this proposal would be a required listing of the ***manufacturer's suggested safe minimum age***. This is an easily recognized measure of product safety, and product liability concerns should keep the numbers fair, even if they are qualified by specifying lower doses.

A statement on precautions addresses the clear desire for consumers to get more information, not less. The DSHEA shows that people are concerned that the FDA might suppress information on potential benefits by restricting claims. What seems to be skimmed over is the ***risk*** side of the equation. While the supplement act improperly puts the burden of substantiating a particular required warning on the FDA, it doesn't exclude a requirement that manufacturers make some statement on their own.

3) The FDA needs a problem tracking database.
This would be similar to the adverse event reporting database for supplements, but for tracking all product complaints reported to the FDA. Finding the right person within the FDA to handle a specific issue is an exercise in frustration. Problems always seem to be deflected to some other division, until a dead end is reached. The current stated policy of CDER, for example, is to avoid any complaints regarding misbranded drugs sold over the internet, unless the product is purchased and mailed to their office, or until someone is physically harmed. The internal offices understandably want all inquiries directed through the front line consumer inquiries division. Once a problem is taken under investigation, details become unavailable without the formality and delay of filing an FOIA request.

Rather than placing the burden on a cooperative outsider to find the right destination within the FDA, it would be helpful if the consumer inquiries division could take down all the info, assign it a tracking number for follow-up, and forward it to the appropriate internal division. Even if it concerns an trade issue, forwarding the complaint to the FTC, and keeping track of their responses, would foster better communication between the two agencies.

The clear public consensus is a desire for more information and choices, mixed with concern that the FDA will take away viable treatments. I strongly believe that the FDA should concentrate on requiring that manufacturers provide adequate information on potential risks to balance their benefit claims. Trying to police the mess after the fact just doesn't work. Requiring a statement of ingredients, and adverse effects will at least make purchasers aware of potential problems. It puts no extra burden of enforcement on the FDA or FTC. In fact, it would surely reduce the number of problems, and save a number of lives in the process.

Thank you for your time,
Ed Anderson