“There is NO CURE for Herpes. RIGHT? Think again! If you’ve been looking for a herpes product that actually delivers on its promises, your search is over.” That’s certainly a bold statement, isn’t it? Makes one curious about what this product is, and what it promises to deliver. Quite a bit as a matter of fact:

“Most people say nothing can completely cure genital herpes (herpes simplex virus). But Genisil All-Natural Cream is entirely different from any other product . . . When applied at the first warning of a pending occurrence (slight tingling or burning sensation), individuals report that the herpes outbreak is avoided.”

Well, no doubt those claims got your attention. As it turns out, they also got the attention of the U.S. Food and Drug Administration (FDA).

In early March, the FDA issued warning letters to the several companies marketing unapproved and misbranded drugs for the prevention and treatment of sexually transmitted infections—including HPV, HIV, chlamydia, and genital herpes. The targeted products are marketed and sold over the Internet to U.S. consumers, in violation of the Federal Food, Drug, and Cosmetic Act. The letters advised the companies in question of the consequences of making fraudulent claims in their marketing materials, including possible criminal prosecution. Among the companies issued letters were those marketing such products as Aviralex, Imulux, Tetrasil, and the product Genisil above, all touted on Internet sites as effective treatments for genital herpes.
The warning letters are a part of the FDA’s ongoing campaign against fraudulent products marketed on the Internet. At issue is the marketing of the products and the claims made as to their effectiveness. As the FDA states in its letter to Aidance Skincare & Topical Solutions, LLC, who market both Genisil and Tetrosil, these products are by definition a drug, “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.” According to FDA regulations, new drugs need to go through a mandatory application process before they can be introduced. According to FAQs posted on www.genisil.com, however, the product falls under another category—cosmetic. In response to the question “Is Genisil FDA approved?” the site posted the following:

No. Genisil is sold as an over-the-counter health product, much like other products you can buy in health food stores and the “alternative” aisle in your local pharmacy. There are often very substantial financial outlays required to take a product through the FDA. Such resources are often only available to large pharmaceutical companies . . . We consider Genisil to fall under the FDA “Cosmetic” product category. Here, products are “intended for the cleansing, beautifying and moisturizing of the human body”. We do not make direct curative claims. All claims are attributed to third parties (customers, physicians, etc.) who tell us they have benefited from its soothing and moisturizing properties. They also appreciate its germicidal aspects.

The FDA disagreed, citing statements that would indicate that the product is “intended to prevent, treat, or cure disease conditions,” including the following, from the genisil.com site: “Genisil is a uniquely formulated all-natural ointment. It contains a patented compound of the most potent natural anti-virals on earth, plus other ingredients that work FAST to resolve herpes issues.”

Another recipient of a warning letter, IMULUX, LLC, was cited for its claims about what the FDA considers a “drug/device combination product,” as it markets Imulux as a treatment involving both an “activating solution” and UV-emission lamp. Statements posted on www.imulux.com for what it termed its “treatment process” included the following:

“IMULUX is a new scientific breakthrough -- proven safe and effective -- that is uniquely able to actually kill all strains of Herpes viruses. Together, the IMULUX treatment components target and kill any strain of herpes virus . . . Even better, IMULUX suppresses further outbreaks for life. At last! Permanent freedom from the full range of upsetting herpes symptoms.”
The FDA granted the companies in question 15 working days from receipt of the letter to respond regarding specific steps taken to address the violations listed in the warning letters. It appears that at least some of the sites have responded. A visit to www.genisil.com in late March revealed significant changes to the site. The address itself redirects automatically to a general site for Aidance Skincare and the product description for Genisil has undergone significant edits. As it currently reads (at press time):

Genisil® is formulated for use in the sensitive, private area of your body. Its all-natural ingredients include natural jojoba oil, beeswax, the tetraSILVER® silver oxide, and a blend of essential oils selected specifically for use on the genitals.

While the site offers some very basic information on genital herpes, there are no longer any claims like the ones cited in the FDA letter. However, the product remains for sale with much of the same marketing language on other Internet sites.

As for www.immulux.com, that site at press time offered tourist and travel information for Palm Beach Florida, with no mention of any herpes-related products or treatments. However, the site www.phototherapyforherpes.com remains active, offering Imulux Treatment Lights and Med Packs (alternately referred to as Photo-therapy for herpes on the site) for sale. While not cited in the FDA letter, the site appears to promote the same products. As the FAQs state, “PHOTO-THERAPY FOR HERPES is a groundbreaking herpes treatment consisting of a safe, non-prescription solution developed by IMULUX LTD and a specially designed ultraviolet (UVA) lamp.”

Additional FAQs on the site are similar to those cited in the FDA letter:

**How effective is PHOTO-THERAPY FOR HERPES?** PHOTO-THERAPY FOR HERPES, in research and development since 1974, has been used to treat thousands of people successfully. In fact 93% of all treatments have proven effective in stopping outbreaks on first application. The success rate rises to 99% on the second treatment. In rare cases three or more applications are required.

**How does PHOTO-THERAPY FOR HERPES compare to anti-virals like Valtrex, Famvir or Acyclovir?** Clinical investigators find the benefits of PHOTO-THERAPY FOR HERPES treatment to exceed any benefits received from conventional accepted medical protocol and treatment regimes.
Both domains, according to WhoIs domain registration records, are owned by Dr. Jon Stoneburner, the owner of a patent for his phototherapy treatment. The Helper contacted Dr. Stoneburner to ask for comment on the violations listed in the FDA warning letter, as well as inquire about the site phototherapyforherpes.com, but had received no response at the time this issue went to print.

One site that appears not to have made any changes since the FDA letter was issued is www.aviralex.com. Statements cited in the FDA warning letter remain on the site, including: “Help STOP the painful, ugly outbreaks of all Herpes related symptoms. With only ONE application of Aviralex.”
At the time this issue went to press, Aviralex, Int. had not responded to our request for their response to the FDA warning letter.

Certainly there are many people with herpes who are interested in alternative treatments and therapies. Claims that time-consuming and expensive bureaucracy may keep potentially beneficial products off the market may resonate with many as well. But glowing user testimonials and skillful marketing cannot take the place of randomized, double-blind, placebo-controlled studies. When evaluating any potential alternative treatment, do your homework. Talk to your doctor. Visit PubMed. Ensure that any treatment you consider is both safe and effective. And always remember, if it seems to be good to be true, it probably is.