BENIGN B6 BEFORE BIOSTRATUM

By Scott C. Tips, General Counsel, NHF

We eat it in foods every day. Admittedly, it might take a different form such as pyridoxine glucoside, or pyridoxine hydrochloride, but it is still Vitamin B6. Humans have consumed this vitamin in their foods since time immemorial. Bananas, fish, chicken, pork, avocados, and peanuts all contain significant quantities of Vitamin B6. Yet, the Food and Drug Administration (FDA) recently declared one form of this vitamin to be a new drug and therefore excludable from dietary supplements.

First isolated in the 1930s, Vitamin B_6 is a water-soluble vitamin that traditionally has been viewed as existing in three forms: pyridoxal, pyridoxine, and pyridoxamine. The Vitamin B complexes that are sold in health-food and other stores typically contain the second form of B6 not the pyridoxamine form. And it was the pyridoxamine form – specifically pyridoxamine dihydrochloride – that the FDA decided was a "new drug."

How It Started

Desperate for cash, after spending more than $100 million of its investors' money over 11 years on a new drug that was nothing more than a form of common Vitamin B6 sold on the internet, BioStratum, Inc. did what any modern American corporation would do – it turned to the government for protection from its competition. After all, it was looking at losing a lucrative $4.4 billion market in the United States alone. More than that, it faced going out of business entirely.

So, on July 29, 2005, BioStratum's law firm filed a Citizen Petition with the FDA citing its right under 21 CFR 10.30 to ask the FDA to: "(1) State in writing that dietary supplements that contain pyridoxamine are adulterated under the Federal Food, Drug, and Cosmetic Act; (2) exercise its enforcement authority under the act to remove from interstate commerce dietary supplements containing pyridoxamine; and (3) not place this citizen petition in the agency's docket for premarket notifications for new dietary ingredients (Docket No. 2004N-0454)."

BioStratum identified itself in the Petition as the manufacturer of Pyridorin (pyridoxamine dihydrochloride), which is the subject of an investigational new drug application (IND) filed with the FDA in July 1999 for use as a therapeutic drug for diabetics. In its Petition, the Company argued that substantial clinical trials had been conducted for the drug, with the studies for the trials having been made public, and that pyridoxamine was never marketed as a dietary supplement or as a food prior to Pyridorin's IND authorization.

The Council for Responsible Nutrition (CRN), an American-based trade organization, immediately filed comments with the FDA challenging BioStratum's Petition and pointing out, among other things, that pyridoxamine is unequivocally a dietary ingredient because it is one of the three primary natural forms of Vitamin B6, and it is one of the two predominant forms in animal products used as human foods. Moreover, CRN – supported by comments filed by Jarrow Formulas – argued that pyridoxamine was on CRN's "gold list" of grandfathered ingredients and that its marketing as a dietary ingredient was entirely consistent with the long history of the science of this form of Vitamin B6. The trade organization and BioStratum dueled it out for years in this FDA corral. But it was a rigged game. In the end, the FDA did not disappoint its pharmaceutical controllers and sided with the pharmaceutical company, ***tentatively*** declaring this form of Vitamin B6 to be a new drug.

How It Really Started

Yet, this was not the first time that the FDA had sided with the pharmaceutical industry against natural products by declaring a natural ingredient to be a drug. Who could forget the FDA's attack against red yeast rice because it contained molecules of lovastatin, an anti-cholesterol ingredient found in prescription drugs (Mevacor and Altocor) approved by the FDA? And who could forget the FDA's ban against ephedrine alkaloids in dietary supplements while leaving untouched across the pharmaceutical aisle more-potent ephedrine-alkaloid drugs in the OTC section of the store?

And even more recently, in April 2008, GlaxoSmithKline filed its own "Citizen" Petition requesting that dietary-supplement weight-loss claims be classified as "disease claims." Citizen petitions were intended to be a formal means for a citizen, or the public, to seek the FDA's action or response on a particular regulatory or health matter. Of late, though, the original intent of citizen petitions has been

perverted by corporate giants to use their own "citizen" petitions to seek FDA protection of their profits from normal market competitive forces. If these pharmaceutical companies are "citizens," then hyenas are ballerinas.

Citizen petitions, then, are just a new and growing tool for the pharmaceutical industry to suppress its whole-foods competitors. Yet, the law itself has handed drug companies like BioStratum an argument for suppressing its competition – that natural ingredients already subject to clinical drug trials cannot be sold as dietary supplements!

The Law

Our own beloved Dietary Supplement Health and Education Act of 1994 (DSHEA) ***itself*** prohibits the inclusion into a dietary supplement of any ingredient "authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food" (Section 201(ff)(3)(B)(ii)). So, this general wording is not new at all; it has been around for more than 14 years.

In its Petition, BioStratum relied upon this Section of the Act to convince the FDA to suppress the marketing and sale of the dietary-supplement version of this vitamin. Unfortunately, neither CRN nor Jarrow were able to convince the FDA that the pyridoxamine form of Vitamin B6 had been marketed as a either a dietary supplement or a food, even though, as Jarrow pointed out among other things in its well-written comments, Brewer's Yeast, sold for decades in health-food stores nationwide and beyond, contains relatively high levels of B-vitamins, *including the pyridoxamine form of B-6*. Unsurprisingly, the FDA – the pharmaceutical industry's best friend – remained unmoved. FDA said the law means more than mere presence in food. The ingredient itself must have been marketed as a food or dietary supplement in order to permit the "grandfather" provision to apply.

The Verdict

On January 12th, the FDA ruled that it "has considered the information and legal argument set forth in the petition. Based on the facts set forth in the petition, the agency tentatively concludes that pyridoxamine, the active moiety ... of pyridoxamine dihydrochloride, is excluded from the dietary supplement definition under the exclusion clause in 21 U.S.C. 321(ff)(3)(B)(ii) and therefore may not be marketed as or in a dietary supplement. However, although the petition asserts that there is no evidence that pyridoxamine was marketed as a dietary ingredient or as a food prior to the authorization of Pyridorin for investigation under an IND, the agency is interested in receiving information, if any, that bears on pyridoxamine's prior marketing as a dietary ingredient or as a food, as well as other information that would inform the agency's final decision on the status of pyridoxamine."

This decision has been encouraging for other pharmaceutical companies seeking to restrict competition. Another drug company has already filed its own citizen petition with the FDA, seeking to declare pyridoxal 5'-phosphate (sold in health-food stores as P5P) to be a new drug also based upon the same legal reasons set forth in the BioStratum petition. This could be the prelude to a general regulatory assault upon dietary-supplement ingredients long naturally found in foods.

What Can be Done

As it stands now, the FDA's decision is tentative and not final. It can, therefore, be changed through further action on the part of consumers and trade-industry groups. Food-and-drug lawyer Todd Harrison of the Washington, D.C.-based firm Venable LLP, notes that in its recent tentative decision the FDA specifically declined to state that supplements containing pyridoxamine are adulterated; instead, the FDA simply said it was a new drug. That is interesting and perhaps significant.

In Harrison's view, at present, there are three main courses the industry or consumers could take: (1) File a lawsuit against the FDA; (2) Continue to sell pyridoxamine and then defend against any FDA enforcement action; or (3) File one's own Citizen Petition giving evidence of prior marketing of the ingredient. I agree with Harrison.

In addition, before BioStratum even existed as a company, let alone launched its drug caper, the pyridoxamine form of Vitamin B6 was being safely consumed by Americans. It is a naturally-occurring and beneficial vitamin. Yet, what BioStratum could never accomplish in a free marketplace, it can and is doing with the aid of the government's iron fist. This is criminal.

Go to the National Health Federation's website at *www.usalone.com/cgi-bin/petition.cgi?pnum=962* to sign our petition telling your Congressmen and -women and your Senators that you will not stand for the FDA banning any more vitamins by turning them into "drugs." Tell them your vote, and hence their political careers, depends upon them putting a stop to this insane misuse of government for private commercial advantage. The time to act is now.