Mr. Paul J. Sage  
Division of Manufacturing and Product Quality (HFD-320)  
Office of Compliance  
Center for Drug Evaluation and Research  
Food and Drug Administration  
7520 Standish Place  
Rockville, Maryland 20855  

Re: Docket No. 84P-0242/CP

Dear Mr. Sage:

This is a final response to your citizen petition dated July 9, 1984, requesting that the agency (a) adopt a new enforcement policy to discourage the marketing, without FDA's approval, of unapproved or inadequately tested drugs by routinely using the criminal provisions of the Federal Food, Drug, and Cosmetic Act (the Act) to punish persons responsible for such practices; and (b) publish this new policy in the Federal Register. In accordance with 21 CFR 10.30(e)(2)(iii) the agency provided a tentative response to your petition on December 24, 1984.

Petitioner's Statement of Grounds

Your petition asserts that there is a perception in the regulated industry that unapproved drugs may be marketed without FDA's approval and without fear of prosecution for violating the law. You state that although the immediate stimulus for this petition is the report of a link between the deaths of 38 infants and the use of the unapproved drug E-Ferol, this is not the first or only inadequately tested, unapproved drug product that has been marketed in recent years. You then discuss starch blockers and bogus Vitamin B-15 preparations as falling into this category and claim that FDA should have used criminal sanctions in both of these cases.

You contend that FDA's policies and regulatory practices have undermined the self-policing "voluntary" deterrence upon which efficient regulation depends. You further contend such policies have encouraged the marketing of questionable, inadequately tested drugs, of which are intended to treat serious illnesses where use of an ineffective drug would be dangerous. Especially in the area of health fraud, you claim companies are making large profits from such illegal activities. You believe that routine use of criminal sanctions would create a needed deterrent effect in combating health fraud. You contend that exclusive use of civil measures to control the marketing of violative products has proven to be inadequate.
Agency Response

We recognize that entrepreneurs may be tempted to take advantage of lax enforcement if they perceive that the risks are minimal. However, the agency does not believe that there is a general perception in the regulated industry that unapproved drugs may be marketed without risk of serious regulatory consequence. Our compliance policy and compliance programs pertaining to new drugs have been widely available and discussed in many forums over the years with the regulated industry.

The agency has in the past been hesitant to invest its scarce resources in a broad health fraud enforcement initiative because other matters had a higher priority. It has, however, consistently dealt aggressively with purveyors of the more egregiously violative products. FDA initiated nation-wide enforcement actions which essentially ended the illegal promotion of starch blockers and pangamic acid. The E-Ferol matter referred to in the petition resulted in a criminal prosecution. In 1987, a Federal grand jury indicted Carter-Glogau Laboratories, Inc., O'Neal, Jones, and Feldman, Inc., and the officials responsible for the production and sale of E-Ferol. After a lengthy trial, the defendants were found guilty of multiple felony violations and are now exposed to stiff sentences. In fiscal year 1987, actions approved by the CDER Health Fraud Branch included 38 regulatory letters, seven seizures, three injunctions, and one grand jury investigation to look into potential criminal violations. This vigorous regulatory activity will continue. The agency believes that a balanced approach afforded by use of a variety of sanctions is more efficient and effective than the single-sanction policy you suggest. Indeed, the uncertainty about the agency's choice of remedy itself creates a deterrent effect. FDA's increasing emphasis on combating health fraud is also reflected in a significant increase in FY 1988 in full-time equivalent field personnel (22 to 43) allocated to health fraud.

In addition to traditional enforcement activity, the agency has mounted a major public education effort to inform consumers about the facts of health fraud. To the degree that education helps reduce the demand for fraudulent health items, it also helps eliminate the problem itself. In this public education effort, FDA has, among other things, helped produce a public service television commercial on quackery and has published pamphlets on fraudulent arthritis cures, health fraud and AIDS, and fraudulent weight loss programs. Although it is difficult to quantify the results of consumer education, the agency believes that the effort has been very effective.

FDA has also participated in conferences designed to build public sector coalitions against health fraud. FDA co-sponsored national conferences on health fraud in Washington, D.C., in 1985 and in Kansas City in 1988. FDA also sponsored a large number of regional health fraud conferences. These conferences brought FDA, Federal Trade Commission, and Postal Service personnel together with officials from State and local agencies.
This represents a national campaign of cooperative and complementary enforcement activity with each federal, state, and local agency utilizing its own unique resources, abilities and enforcement methods to best effectuate the common goal.

Even if FDA resources were unlimited, we would not necessarily agree there is an optimal number of criminal prosecutions to achieve a deterrent effect. Further, the agency cannot unilaterally decide to bring "[s]mall cases that focus on one, two or a few violative products [that] are relatively easy to develop and present." Agency experience suggests that to get Department of Justice approval to file criminal charges and then to obtain significant criminal penalties, we must develop cases that represent a substantial risk to the public health or significant economic harm. It has also been the agency's experience that the courts' reaction to small cases is to impose small fines (and no jail time). Thus, it often appears that greater deterrence is obtained by forcing a cessation of distribution -- by administrative or civil means -- that had been generating large profits.

In summary, your July 9, 1984 citizen petition advocates FDA adopt a new, more aggressive, enforcement policy to discourage the marketing of unapproved new drugs and the promotion of fraudulent products by emphasizing criminal prosecution as a deterrent. To implement the proposed policy you requested that the Commissioner issue a policy statement giving affected persons notice that the agency intends to more routinely use criminal provisions of the Act. The agency has concluded the flexible application of all enforcement options is preferable to focusing on criminal prosecution; therefore, FDA denies your request that it issue the proposed policy statement. The agency believes, however, it has taken action consistent with your general view that a more aggressive enforcement posture is desirable. The Action Plan I goal on health fraud and the Action Plan II goal on improving enforcement processes were designed, in part, to achieve greater deterrence of violations. The publicity generated by the agency to inform our constituencies of action plan goals has provided notice of the potential consequences of violative conduct. Administrative and civil actions involving unapproved products are increasing, and when they do not have the desired salutary effect, FDA and cooperating agencies, working together, have demonstrated that criminal cases will be initiated.

We sincerely respect your views and motivation in filing this petition and your continued dedication to consumer protection. We apologize for the excessive amount of time it has taken to respond to your petition. A copy of this response will be on public display.

Sincerely yours,

John M. Taylor
Associate Commissioner
for Regulatory Affairs