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May 24,1999

Dockets Management Branch
Food & Drug Administration HFA-305
5630 Fishers Lane, Room 1061
Rockville MD 20852

Re: Dkt. 99N-1174
Dietary Supplements

Dear CFSAN:

These individual comments will focus on item 7 of your invitation for written comments. I regret that I cannot attend the June 8 meeting because of other commitments.

"7. *Given FDA's limited resources, what mechanisms are available, or should be developed, to leverage FDA's resources to meet effectively the objective of the strategy?*"

Enforcement by well-publicized selective deterrence is the best strategy in light of the ill-considered DSHEA law's handcuffs on FDA civil enforcement. In summary, I propose the Commissioner adopt a five step program:

1. Set a goal of three targeted FDA-DoJ criminal prosecutions each fiscal year, against high-profile dietary supplement companies and their chief executives using traditional FDA case law for prosecuting fraudulent and misleading statements, and enhanced prison sentences under the Sentencing Guidelines for the executives. Deterrence by

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criminal prosecution has remarkably sobering effects. FDA has long received judicial deference to its broad interpretation of "misleading" in section 403 and it won several criminal cases in similar circumstances of excessive efficacy claims in the past. Publicity about the criminal actions will deter other violators.

2. Set a goal of at least three FDA-assisted, FTC-initiated injunctive actions each fiscal year demanding disgorgement of profits and consumer restitution against high-profile dietary supplement companies; their advertising agencies; and the chief executives of both entities, for materially misleading advertising of dietary supplements. Attack the advertising agency as FTC has done in the past. The deterrent effect will be quite clear to infomercial producers and "creative" claims writers nationwide. A little enforcement will go a long way.

3. Set a goal of at least three FDA-assisted, USPS Post Inspection Service enforcement cases each fiscal year against high-profile dietary supplement companies and their chief executives using traditional USPS mail fraud case law, to block mail delivery of further promotional mailings and provide consumer refunds for the use of the mails in making fraudulent and misleading statements about efficacy of dietary supplements. USPS tools are extremely effective because the mail-hold relief and administrative hearings are faster and more impactful than court cases.

4. Set a goal of at least three FDA-assisted Customs Service punitive enforcement cases each fiscal year against the importers of record and consignees of imported active ingredients that are offered for importation with labels and shipping papers falsely classifying them as foods and/or containing package labels making false claims of dietary supplement efficacy. The power of OASIS to block the fraud by choking the supply chain is underutilized.

5. The Commissioner should convene quarterly or more frequent meetings of an Elder Fraud Enforcement Forum in which policy level managers of the FDA, FTC, USPS, Customs, and the Justice Department's Consumer Affairs and Fraud Sections meet with the National Association of Attorneys General to coordinate the deterrence of misleading claims by dietary supplement marketers.

BASIS FOR THE RECOMMENDATIONS

1. Some dietary supplement marketers deserve to be punished for their fraudulent taking of money from consumers, especially elders, who will not obtain the claimed health

benefit from the product (and who may be harming their health by eschewing NDA drugs in favor of consuming the diet supplements in reliance on product claims).

DSHEA is a discontinuity in the history of American consumer protection legislation. At the very end of a long congressional session, after much misinformation and elaborate lobbying efforts, Congress chose to restrain FDA's civil enforcement power over dietary supplements. This flawed aberration contravened FDA's history of consumer protection. DSHEA shields the less scrupulous marketers of these products from the kinds of control measures that courts had frequently endorsed when charges were brought by FDA food enforcers over many decades.

The Commissioner should choose to act before the vacuum of regulatory authority is filled with stories of fraud and overreaching by marketers. Acknowledging that dietary supplement marketers won the DSHEA legislative fight, but observing the misleading and fraudulent sales pitch to elders that pervades this field of marketing claims today, the FDA should act. The Chief Counsel should dust off the Park and Dotterweich doctrines and ask the Justice Department to bring criminal informations or indictments against the most willful and egregious marketers. (A goal of at least 3 cases a year is modest but manageable with current resources.)

The individual criminal power given FDA by courts interpreting the FD&C Act carries none of the DSHEA constraints and has all of the ripple effect of deterrence that the Park doctrine of individual liability had on food warehouse owners in the 1970s and 1980s. A Sentencing Guideline for CEO prison time and for consumer restitution should make clear that criminal fraud does not pay. CFSAN's Question 7 asked about "leverage". Deterrence with a bite is the best way to leverage the statutory power to punish miscreants, despite the flaws of DSHEA.

2. The FTC's civil injunctive power to order consumer redress and disgorgement of profits by the violative marketer is a potent weapon untouched by DSHEA's constraints on FDA. But historic patterns of FTC-FDA cooperation need to be attuned to the DSHEA constraint on FDA's civil statutory options.

Where an excessively aggressive efficacy advertisement for a nutritional product is aimed at a particularly vulnerable subpopulation such as the elderly, the FTC has the policies in place to support enforcement; it needs the laboratory and witness support that CFSAN and the FDA National Forensic Chemistry Lab can provide. When the FDA "lends" the technical support to FTC it is acting within statutory authority and interagency MoU's and does not need to deal with the flaws in DSHEA limits on FDA civil remedies.

3. Many of the misleading advertising claims disseminated to elders and other credulous subpopulations of diet supplement users invite response by mail, or phone with product delivery via mail. Postal inspectors have statutory authority to administratively prosecute such frauds. They need FDA technical support to use special remedies such as freezing further deliveries of mail to the marketer and barring the marketer from using bulk mail in furtherance of its scheme. USPS also has the expertise to deliver a fully supported mail fraud case to local Asst. U.S. Attorneys where warranted. FDA's leverage of its technical abilities should properly be used with the Postal Inspection Service tools to halt the diet supplement marketer's misleading campaign. A little FDA help will go a long way.

4. The Customs Service, working with FDA on the OASIS system, should "flag" suspect incoming ingredients and packaged items according to TSUS subclassifications, and utilize both Customs penal bonds and FDA "Notice of Detention & Hearing" processes. The targets would be diet supplements that have shown safety concerns (or analogues thereto such as the recent GBL products, see Talk Paper T99-21, 5/11/99) for which a block on importation chokes the supply line of the fraudulent marketer. Customs also should prosecute the fraudulent representations on incoming packages that compare the alleged diet supplement to a drug product or that purport to offer drug benefits, where the product lacks an NDA number or drug listing number. Because import sourcing is less protected constitutionally than domestic commerce, FDA and Customs can act more rapidly at ports of entry to forestall the misleading marketing practices.

5. Un-coordinated enforcement is worse than none at all. The use of an Elder Fraud Enforcement Forum is optimal. The group would benefit from the sharing by policy level managers of the FDA (especially ORA, CFSAN, OCI and OGC),

FTC, USPS, Customs, and the Justice Department's Consumer Affairs and Fraud Sections. These federal enforcement entities should meet with the National Association of Attorneys General to coordinate the target selection goal, which is the deterrence of misleading claims by dietary supplement marketers. NAAG members can simultaneously file state enforcement cases against the violators while the federal actions are pending, since they represent a separate sovereign entity (and often have restitution authority).

CONCLUSION

CFSAN should recommend to the Commissioner that, as part of the DSHEA strategy, inter-agency coordinated enforcement tools should be deployed against the minority of diet supplement companies that engage in 403(a)(1) fraudulent and misleading claims. Potent weapons like individual CEO prison sentences, consumer restitution, mail blocks and ingredient/package import holds are among the tools available. They can and should be used.

The present lack of coordination among the multiple regulators is a disservice to the public. The strategy needs to overcome the results of past lobbying efforts of the diet supplement industry and to direct a forceful cleanup of a billion-dollar marketplace currently struggling with significant deceptive practices.

For more detail, please see volume 1 of my treatise, Food & Drug Administration (2d Ed., West, 1998 Supp.), and my text Lawyers' Guide to Elder Injury & Accident Compensation (Amer. Bar Assn. Press). Thank you for considering these individual views.

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