



MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
Center for Drugs & Biologics

DLC

Drugs and Biologics Fraud Bulletin #5

DATE : March 28, 1985

FROM : ACTING CHIEF  
DRUGS AND BIOLOGICS FRAUD BRANCH (HFN-316)

SUBJECT: IMPLEMENTATION OF CLASS ACTION TO ISSUE REGULATORY LETTERS  
TO ALL FIRMS MARKETING DHEA

TO : ALL REGIONAL DIRECTORS  
ALL DISTRICT DIRECTORS  
ALL STATION CHIEFS  
ATTN: ALL COMPLIANCE BRANCH DIRECTORS  
ALL INSPECTION BRANCH DIRECTORS

PURPOSE

DLC-Rx Drug Study Bulletin #265 issued July 9, 1984 provides the background information for this action document. This DBF Bulletin #5 authorizes district to issue regulatory letters to all manufacturers and distributors of D.H.E.A., where appropriate. The major changes from DLC-Rx Bulletin #265 are

1. Each district will be responsible for evidentiary support of the charges in each letter. This should include a physical sample to test and analyze for DHEA content (if necessary) and appropriate basis for a showing (to the court) of intended use under section 201(g).
2. We recommend inspection of each identified manufacturer or producer of the new drug substance (DHEA) to determine the test method to be used to assure the claimed purity and potency of the product. This documentation is necessary since there is no legally recognized "standard" for DHEA and test methods for assuring the identity, purity and potency of dehydroepiandrosterone in organic products have not been established or recognized by the scientific community. Please refer this information to the national coordinator.
3. The model letter attached has been revised to include a 502(f)(1) charge that the articles lack adequate directions for use. A 502(a) charge may be added if the district feels it can be supported in any specific instance.

4. This action approves the recommendations for issuance of a regulatory letter by the following districts under the conditions outlined in paragraphs 1 and 2 above.:

- A. BROOKLYN DISTRICT  
to Phoenix Laboratories, Inc. - 85-323-173
- B. ORLANDO DISTRICT  
to Athena Products - 84-374-301 et al.
- C. ORLANDO DISTRICT  
to Life Extension Clinics - 85-374-310
- D. PHILADELPHIA DISTRICT :  
to J.N.S. Delaveau - 84-367-934/936

We appreciate their recommendations for issuance of regulatory letters to these firms.

5. In coordination and conjunction with the issuance of the first regulatory letter by a district on D.H.E.A., the Agency will issue a Press Release. Therefore, it is important for the National Coordinator to be notified by telephone in advance of the date the regulatory letter will issue.

All questions or inquiries concerning this action against DHEA products and copies of all regulatory letters and replies should be directed to the National Coordinator, Arthur E. Auer (MFN-315) FTS: 8-443-7333.

Arthur E. Auer

Attachments

- Tab A - Model Regulatory letter
- Tab B - List of Firms processing D.H.E.A.
- Tab C - Tufts University Information on DHEA  
Draft Press Release

AE Auer: zah: 2/12/85: 2/20/85: 3/10/85: 3/27/85

R/D Init: AJ Aronson: 3/26/85

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1/9/63  
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PRESS RELEASE 4/9/85: DHEA AN UNAPPROVED NEW DRUG THAT REQUIRE PREMARKET  
APPROVAL

FDA NO.: P85-12  
SOURCE: FOI SERVICES FULL TEXT (FT)  
DOCUMENT TYPE: PRESS RELEASES (PRL) Press Release  
PUBLICATION DATE: 850409

TEXT:

The Food and Drug Administration today instructed manufacturers and distributors of the drug DHEA, which is promoted as a "natural" weight reduction product, to discontinue selling it because it has not been reviewed for safety and effectiveness.

DHEA, known as dehydroepiandrosterone or dehydroandrosterone, is a steroidal hormone which has been sold nationwide without prescription in retail stores and through the mails for weight management, enhanced sex life and longer life. It has been promoted in recently popular books on extending human life. But no evidence has been submitted to FDA which substantiates those claims.

FDA is writing makers and distributors that DHEA is an unapproved new drug and that they must stop selling it and must provide FDA with information about its manufacture and distribution. If the companies fail to comply within 10 days of receipt of the letter, FDA will consider regulatory actions against the products and companies.

FDA has few adverse reaction reports on the drug, but said the risks from long-term use are unknown. DHEA may be manufactured from human urine. Scientific studies have not established what effect reintroducing into the body this concentrated bodily excess might have, FDA said.

No applications to conduct human studies with DHEA or to market it were submitted to FDA by the companies now selling it. The substance is considered a drug because under the Federal Food, Drug and Cosmetic Act, a substance that is offered for a nonfood purpose and that is intended or advertised to affect the body's normal functioning is classified as a drug. All new drugs require premarket approval.

For more information contact Bruce Brown, 301-443-3285.

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DOCUMENT TYPE: TALK PAPERS (TLP) Talk Paper

PUBLICATION DATE: 850424

IDENTIFIERS: HEALTH FRAUD PROGRAM

TEXT:

The article, "Foods, Drugs or Frauds" in the May issue of Consumers (CR) magazine discusses fraudulent claims for products consumers shouldn't waste their money on. The Commissioner's April 16 letter to CR (attached) may be used to answer questions. In addition, the following points can be made: --The agency has an active, ongoing health fraud program, utilizing both regulatory actions and consumer education. Actions in 1983 were 70 seizures, 3 injunctions and one prosecution and in 1984 were 24 seizures, 3 injunctions and 3 prosecutions. Further, at least two dozen educational publications have been developed or updated and made available to the public. --Many of the products mentioned in the article were known to FDA before and were under investigation, covered by the OTC drug review or already acted against FDA. Those new to the agency will be scheduled for coverage in the future. --Education works. On October 1984 Roper Report national opinion survey found that most Americans have never heard of most economic health frauds. Of those who have, the overwhelming majority don't believe that the products are effective. --The company featured on the magazine's cover, Life Extension Products and Services, is part of a network of firms, many of which operate out of south Florida promoting Gerovital and other drugs. The address given for the firm is a mail drop, not a plant or warehouse that FDA can easily investigate and take action against. However, FDA had investigated this network of firms and brought enforcement action against one of the larger operators. There is an Import Alert banning all importation of Gerovital into the U.S. --CR's report is largely based on literature sent to a mock retail store, NOT to a prospective consumer. Although the former may be actionable, wholesalers' claims often differ from those in either product labeling or public advertising designed for retail promotion. --Prosecutions cannot provide immediate consumer protection. In advocating more frequent prosecution of quacks, CR fails to note that while a criminal prosecution case is proceeding -- usually over several years -- the suspect products may remain on the market for sale to new victims, and the culprits remain free to market new products. FDA often chooses to protect the public health by swifter seizures and injunctions to remove products from commerce and prevent continuing violations. --FDA's policy against health fraud is to act immediately against life-threatening products, quickly against health-threatening ones and when resources permit against various forms of economic fraud. The majority of the products mentioned by Consumer Reports fall in the last category. The magazine piece did not mention any of FDA's successes and extensive resource utilization against the more serious forms of health fraud. --In the area of drugs alone, The Center for Drugs and Biologics Fraud Branch has processed eight seizures and 22 regulatory letters (involving more than 100 products) since its creation last September. --CR fails to mention FDA's considerable educational efforts including the 1984 breakthrough of having regulated, legitimate industry (via the Pharmaceutical Advertising Council) directly involved for the first time in the fight against health fraud. The longest lasting effect to be had against quacks is to reduce public demand for their products by "vaccinating" the public to be wary of the latest medical "miracles" promoted through the mails and in retail stores. --Finally, CR fails to recommend what resources should be diverted by FDA in order to increase regulatory activity against health frauds. Should more be done against health frauds by FDA if resources must be taken from the serious public health challenges of sulfites, salmonella, pesticides in imports, GMP inspection violations and the predictable but unknown intermittent emergencies such as product tamperings?

Contact Bruce Brown, 301-443-3285 Letters to the Editor

Consumer Reports

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Mount Vernon, NY 10553

The May CR presented an informative look at quackery, but overlooked significant anti-fraud activity. For example, a seven-count criminal indictment returned in Buffalo Nov. 14 may help curb many of the abuses you reported. The case involves off-label claims for a single product, evening primrose oil, promoted for high blood pressure, arthritis and multiple sclerosis. A government victory in this case, in behalf of the consumer, could help deter many of the promotions in your article.

In some other recent actions, the Food and Drug Administration:

--kept unproved "sobriety aids" from getting on the market;

--seized \$2.4 million in products a large mail-order company promoted to enhance breasts, remove cellulite, build muscles and produce fast weight-loss;

--acted against starch blockers and their sister "weight loss" products, DHEA and CCK;

--cooperated with New York and California in blocking a burgeoning "cottage industry" in unproved cytotoxicity allergy testing (using blood samples);

--sought grand jury investigations involving two cases of felony

violations related to laetrile and calcium pangamate.

There are more such actions in the offing from the new FDA Fraud Branch which we set up last fall. Your full-page quackery chart lists a number of products and companies under FDA investigation. Indeed, increased activity against quackery is one of FDA's ten top priorities in our soon-to-be-released Action Plan.

As CR noted, like all government agencies, FDA has limited resources and has had to set priorities -- giving our first attention to life-threatening situations. We'll never be able to seize every fraudulently promoted product. But acting with the FTC, Postal Service, Customs, FBI and other federal, state and local agencies, we have forced the most dangerous quack operators out of the country. As Congressman Pepper's hearing made plain last year, these quacks often operate beyond U.S. borders and the reach of U.S. laws. We will never be able to protect persons who go beyond our borders. We will never be able to keep people from being duped by all the clever domestic quacks who keep one step ahead of the law.

That's why, in addition to enforcement action FDA and the Better Business Bureau ask consumers -- and media ad managers -- to call us for information about any product that seems too good to be true. That is why, we also are working with the Pharmaceutical Advertising Council and ad agencies to develop a campaign -- over and above the educational materials we already sent out -- that would help "vaccinate" the public against health fraud, here or abroad.

To that end, having surveyed the field, could Consumer Reports now begin to carry regular features on health frauds -- and how to spot them?

Sincerely,  
Frank E. Young, M.D., Ph.D.  
Commissioner of Food and Drugs