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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P85-12
FOR IMMEDIATE RELEASE
April 9, 1985

Food and Drug Administration
Bruce Brown -- (301) 443-3285
(Home) -- (301) 384-0426

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 body's normal functioning is classified as a drug. All new drugs require premarket approval.

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5) Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Your reply should be directed to Jerome Bressler, Acting Director, Compliance Branch, with a copy to:

Arthur E. Auer, National Coordinator
Drugs and Biologics Fraud Branch/HFN-316
Division of Drug Labeling Compliance
Office of Compliance - Center for Drugs and Biologics
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,
Mary K. Harlin
District Director

1/9/55
DIALOG(R) File 158: DIOGENES
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00026054 00185486
REGULATORY LETTER 4/24/85 TO BARTH VITAMIN: DHEA COMPLEX TABLETS
DRUG BRAND NAME(S): BARTH'S DHEA COMPLEX
DRUG GENERIC NAME: DEHYDROEPIANDROSTERONE. DHEA
SOURCE: FOI SERVICES FULL TEXT (FT).
DOCUMENT TYPE: REGULATORY ACTION (REG)
PUBLICATION DATE: 850424

TEXT:
MICHAEL ASHKIN, PRESIDENT
BARTH VITAMIN CORPORATION
270 WEST MERRICK ROAD
VALLEY STREAM, NEW YORK 11582

DEAR MR. ASHKIN:

IT IS OUR INFORMATION THAT YOUR FIRM IS DISTRIBUTING THE PRODUCT DHEA COMPLEX

TABLETS, 500 MG. UNDER THE LABEL NAME "BARTH'S DHEA COMPLEX". THE LABEL FOR THIS PRODUCT STATES THAT IT CONTAINS DEHYDROEPIANDROSTERONE (DHEA).

THE INGREDIENT, DHEA, IS CLASSIFIED AS A STEROIDAL HORMONE AND THEREFORE IS REGARDED AS A DRUG WITHIN THE MEANING OF SECTION 201(g) OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT (THE ACT). FURTHER, SINCE THIS DRUG IS NOT GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE FOR THE ABOVE REFERENCED CLAIMS OR ANY OTHER THERAPEUTIC CLAIMS, IT IS A NEW DRUG WITHIN THE MEANING OF SECTIONS 201(p) AND 505(a) OF THE ACT.

IN VIEW OF THE ABOVE, THE ARTICLE, DHEA COMPLEX TABLETS, 500 MG., AS A DRUG, IS IN VIOLATION OF THE ACT, AS FOLLOWS:

SECTION 505(a): THE ARTICLE IS A NEW DRUG WHICH MAY NOT BE INTRODUCED OR DELIVERED FOR INTRODUCTION INTO INTERSTATE COMMERCE UNDER SECTION 505(a) OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT, SINCE IT IS A NEW DRUG WITHIN THE MEANING

OF SECTION 201(p) OF THE ACT AND NO APPROVAL OF AN APPLICATION FILED PURSUANT

TO SECTION 505(b) IS EFFECTIVE FOR SUCH DRUG, AND NO NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION UNDER SECTION 505(i) AND REGULATION 21 CFR 312.1 IS ON FILE FOR SUCH DRUG.

SECTION 502(f)(1): THE ARTICLE IS MISBRANDED IN THAT THE LABELING FAILS TO BEAR ADEQUATE DIRECTIONS FOR USE FOR THE CONDITIONS FOR WHICH IT IS OFFERED AND IT IS NOT EXEMPT FROM THIS REQUIREMENT UNDER REGULATION 21 CFR 201.115 SINCE THE ARTICLE IS A NEW DRUG WITHIN THE MEANING OF SECTION 201(p) AND NO APPROVAL OF AN APPLICATION FILED PURSUANT TO SECTION 505(b) IS EFFECTIVE FOR THIS ARTICLE.

WE REQUEST THAT YOU REPLY WITHIN TEN (10) DAYS OF YOUR RECEIPT OF THIS LETTER STATING THE ACTION YOU WILL TAKE TO DISCONTINUE THE MARKETING OF THIS DRUG PRODUCT. IF SUCH CORRECTIVE ACTION IS NOT PROMPTLY UNDERTAKEN, THE FOOD AND DRUG ADMINISTRATION IS PREPARED TO INITIATE LEGAL ACTION TO ENFORCE THE LAW. THE ACT PROVIDES FOR SEIZURE OF ILLEGAL PRODUCTS AND INJUNCTION AGAINST THE MANUFACTURER OR DISTRIBUTOR OF ILLEGAL PRODUCTS (21 U.S.C. 332 AND 334)

WE REQUEST THAT YOUR REPLY INCLUDE:

1) AN ESTIMATE OF THE QUANTITY OF THE DRUG MANUFACTURED OR RECEIVED WITHIN THE PAST TWELVE (12) MONTHS.

2) AN ESTIMATE OF THE SIZE AND FREQUENCY OF SHIPMENTS MADE BY YOU IN THE PAST (12) MONTHS.

3) AN ESTIMATE OF THE AMOUNT OF THE DRUG THAT IS IN INVENTORY UNDER YOUR CONTROL AND OF THE AMOUNTS THAT REMAIN IN CHANNELS OF DISTRIBUTION OUTSIDE OF YOUR CONTROL.

4) THE DATE OF DISCONTINUANCE IN THE EVENT THAT YOU HAVE ALREADY DISCONTINUED MARKETING OF THIS DRUG PRODUCT.

5) YOUR INTENTION WITH RESPECT TO THE DISPOSITION OF YOUR INVENTORIES AND OUTSTANDING STOCKS IN TRADE CHANNELS.

YOUR REPLY SHOULD BE DIRECTED TO MR. CLARENCE L. WALTROUS, DIRECTOR,

COMPLIANCE BRANCH, AT THE ABOVE ADDRESS, WITH A COPY TO:
ARTHUR T. AUER, NATIONAL COORDINATOR
DRUGS AND BIOLOGICS FRAUD BRANCH (HFN-316)
DIVISION OF DRUG LABELING COMPLIANCE
CENTER FOR DRUGS AND BIOLOGICS
5600 FISHERS LANE
ROCKVILLE, MD 20857
SINCERELY YOURS,
GEORGE J. GERSTENBERG
DISTRICT DIRECTOR
FOOD AND DRUG ADMINISTRATION

1/9/56
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00026053 00185485
REGULATORY LETTER 4/24/85 TO BEDFORD VITAMIN: BEDFORD DHEA COMPLEX
DRUG BRAND NAME(S): BEDFORD DHEA COMPLEX
DRUG GENERIC NAME: DHEA COMPLEX. DEHYDROEPIANDROSTERONE
COMPANY NAME: BEDFORD VALLEY STREAM, NEW YORK
SOURCE: FOI SERVICES FULL TEXT (FT).
DOCUMENT TYPE: REGULATORY ACTION (REG)
PUBLICATION DATE: 850424

TEXT:
DEAR MR. ASHKIN:
IT IS OUR INFORMATION THAT YOUR FIRM IS DISTRIBUTING THE PRODUCT DHEA COMPLEX

TABLETS, 500 MG. UNDER THE LABEL NAME "BEDFORD DHEA COMPLEX". THE LABEL FOR THIS PRODUCT STATES THAT IT CONTAINS DEHYDROEPIANDROSTERONE (DHEA).

THE INGREDIENT, DHEA, IS CLASSED AS A STEROIDAL HORMONE AND THEREFORE IS REGARDED AS A DRUG WITHIN THE MEANING OF SECTION 201(g) OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT (THE ACT). FURTHER, SINCE THIS DRUG IS NOT GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE FOR THE ABOVE REFERENCED CLAIMS OR ANY OTHER THERAPEUTIC CLAIMS, IT IS A NEW DRUG WITHIN THE MEANING OF SECTIONS 201(p) AND 505(a) OF THE ACT.

IN VIEW OF THE ABOVE, THE ARTICLE, DHEA COMPLEX TABLETS, 500 MG., AS A DRUG, IS IN VIOLATION OF THE ACT, AS FOLLOWS:

SECTION 505(a): THE ARTICLE IS A NEW DRUG WHICH MAY NOT BE INTRODUCED OR DELIVERED FOR INTRODUCTION INTO INTERSTATE COMMERCE UNDER SECTION 505(a) OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT, SINCE IT IS A NEW DRUG WITHIN THE MEANING

OF SECTION 201(p) OF THE ACT AND NO APPROVAL OF AN APPLICATION FILED PURSUANT

TO SECTION 505(b) IS EFFECTIVE FOR SUCH DRUG, AND NO NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION UNDER SECTION 505(i) AND REGULATION 21 CFR 312.1 IS ON FILE FOR SUCH DRUG.

SECTION 502(f)(1): THE ARTICLE IS MISBRANDED IN THAT THE LABELING FAILS TO BEAR ADEQUATE DIRECTIONS FOR USE FOR THE CONDITIONS FOR WHICH IT IS OFFERED AND IT IS NOT EXEMPT FROM THIS REQUIREMENT UNDER REGULATION 21 CFR 201.115 SINCE THE ARTICLE IS A NEW DRUG WITHIN THE MEANING OF SECTION 201(p) AND NO APPROVAL OF AN APPLICATION FILED PURSUANT TO SECTION 505(b) IS EFFECTIVE FOR THIS ARTICLE.

WE REQUEST THAT YOU REPLY WITHIN TEN (10) DAYS OF YOUR RECEIPT OF THIS LETTER STATING THE ACTION YOU WILL TAKE TO DISCONTINUE THE MARKETING OF THIS DRUG PRODUCT. IF SUCH CORRECTIVE ACTION IS NOT PROMPTLY UNDERTAKEN, THE FOOD AND DRUG ADMINISTRATION IS PREPARED TO INITIATE LEGAL ACTION TO ENFORCE THE LAW. THE ACT PROVIDES FOR SEIZURE OF ILLEGAL PRODUCTS AND INJUNCTION AGAINST THE MANUFACTURER OR DISTRIBUTOR OF ILLEGAL PRODUCTS (21 U.S.C. 332 AND 334)

WE REQUEST THAT YOUR REPLY INCLUDE:

1) AN ESTIMATE OF THE QUANTITY OF THE DRUG MANUFACTURED OR RECEIVED WITHIN THE PAST TWELVE (12) MONTHS.

2) AN ESTIMATE OF THE SIZE AND FREQUENCY OF SHIPMENTS MADE BY YOU IN THE PAST (12) MONTHS.

3) AN ESTIMATE OF THE AMOUNT OF THE DRUG THAT IS IN INVENTORY UNDER YOUR CONTROL AND OF THE AMOUNTS THAT REMAIN IN CHANNELS OF DISTRIBUTION OUTSIDE OF YOUR CONTROL.

4) THE DATE OF DISCONTINUANCE IN THE EVENT THAT YOU HAVE ALREADY DISCONTINUED MARKETING OF THIS DRUG PRODUCT.

5) YOUR INTENTION WITH RESPECT TO THE DISPOSITION OF YOUR INVENTORIES AND OUTSTANDING STOCKS IN TRADE CHANNELS.

YOUR REPLY SHOULD BE DIRECTED TO MR. CLARENCE L. WALTROUS, DIRECTOR, COMPLIANCE BRANCH, AT THE ABOVE ADDRESS, WITH A COPY TO:

ARTHUR T. AUER, NATIONAL COORDINATOR
DRUGS AND BIOLOGICS FRAUD BRANCH (HFN-316)
DIVISION OF DRUG LABELING COMPLIANCE
CENTER FOR DRUGS AND BIOLOGICS
5600 FISHERS LANE
ROCKVILLE, MD 20857

SINCERELY YOURS,
GEORGE J. GERSTENBERG
DISTRICT DIRECTOR
FOOD AND DRUG ADMINISTRATION

1/9/57
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00026047 00185479
REGULATORY LETTER 5/9/85 TO VITAMIN RESEARCH: DHEA 14
DRUG BRAND NAME(S): DHEA 14
DRUG GENERIC NAME: DHEA, DEHYDROEPIANDROSTERONE
COMPANY NAME: VITAMIN RESEARCH MOUNTAIN VIEW, CALIFORNIA
SOURCE: FOI SERVICES FULL TEXT (FT).
DOCUMENT TYPE: REGULATORY ACTION (REG)
PUBLICATION DATE: 850509

TEXT:
VITAMIN RESEARCH PRODUCT
2044 OLD MIDDLEFIELD WAY
MOUNTAIN VIEW, CA 94043
ATTENTION: ALMAR CHANG, PRESIDENT
PRODUCT: VITAMIN RESEARCH PRODUCTS DHEA 14
DEAR MS. CHANG:

IT IS OUR INFORMATION THAT YOUR FIRM IS MANUFACTURING AND OR DISTRIBUTING THE PRODUCT DHEA 14. THE CATALOG LABELING FOR THIS PRODUCT STATES THAT IT CONTAINS DEHYDROEPIANDROSTERONE (DHEA). THE LABELING ALSO STATES THAT IT IS A WEIGHT LOSS PRODUCT WHICH WORKS AS AN APPETITE SUPPRESSANT WHICH ALTERS THE WAY YOUR BODY BURNS FATS AND CARBOHYDRATES. IT SUGGESTS AND IMPLIES THAT IT WILL PREVENT MANY AGE RELATED DISEASES AND ADULT ONSET OBESITY.

THE INGREDIENT, DEHYDROEPIANDROSTERONE (DHEA), IS CLASSED AS A STEROIDAL HORMONE AND THEREFORE WHEN INTENDED FOR DRUG USE IS REGARDED AS A DRUG WITHIN THE MEANING OF SECTION 201(g) OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT. FURTHER, SINCE THIS DRUG IS NOT GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE FOR THE ABOVE REFERENCED CLAIMS OR ANY OTHER CLAIMS, IT IS A NEW DRUG WITHIN THE MEANING OF SECTIONS 201(p) AND 505(a) OF THE ACT.

IN VIEW OF THE ABOVE, THE ARTICLE VITAMIN RESEARCH PRODUCTS DHEA 14, AS A DRUG, IS IN VIOLATION OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT AS FOLLOWS:

SECTION 505(a): THE ARTICLE IS A NEW DRUG WHICH MAY NOT BE INTRODUCED OR DELIVERED FOR INTRODUCTION INTO INTERSTATE COMMERCE UNDER SECTION 505(a) OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT, SINCE IT IS A NEW DRUG WITHIN THE MEANING

OF SECTION 201(p) OF THE ACT AND NO APPROVAL OF AN APPLICATION FILED PURSUANT

TO SECTION 505(b) IS EFFECTIVE FOR SUCH DRUGS, AND NO NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION UNDER SECTION 505(i) AND REGULATION 21 CFR 312.1 IS ON FILE FOR SUCH DRUGS.

SECTION 502(f)(1): THE ARTICLES ARE MISBRANDED IN THAT THE LABELING FAILS TO BEAR ADEQUATE DIRECTIONS FOR USE FOR THE CONDITIONS FOR WHICH IT IS OFFERED IN ITS PROMOTIONAL MATERIAL AND THEY ARE NOT EXEMPT FROM THIS REQUIREMENT UNDER

REGULATION 21 CFR 201.115 SINCE THE ARTICLES ARE NEW DRUGS WITHIN THE MEANING

OF SECTION 201(p) AND NO APPROVAL OF AN APPLICATION FILED PURSUANT TO SECTION 505(b) IS EFFECTIVE FOR THESE ARTICLES.

WE REQUEST THAT YOU REPLY WITHIN TEN (10) DAYS OF YOUR RECEIPT OF THIS LETTER STATING THE ACTION YOU WILL TAKE TO DISCONTINUE THE MARKETING OF THIS DRUG PRODUCT. IF SUCH CORRECTIVE ACTION IS NOT PROMPTLY UNDERTAKEN, THE FOOD AND DRUG ADMINISTRATION IS PREPARED TO INITIATE LEGAL ACTION TO ENFORCE THE LAW. THE ACT PROVIDES FOR SEIZURE OF ILLEGAL PRODUCTS AND INJUNCTION AGAINST THE MANUFACTURER OR DISTRIBUTOR OF ILLEGAL PRODUCTS (21 U.S.C. 332 AND 334)

WE REQUEST THAT YOUR REPLY INCLUDE:

1) AN ESTIMATE OF THE QUANTITY OF THE DRUG MANUFACTURED OR RECEIVED WITHIN THE PAST TWELVE (12) MONTHS.

2) AN ESTIMATE OF THE SIZE AND FREQUENCY OF SHIPMENTS MADE BY YOU IN THE PAST (12) MONTHS.

3) AN ESTIMATE OF THE AMOUNT OF THE DRUG THAT IS IN INVENTORY UNDER YOUR CONTROL AND OF THE AMOUNTS THAT REMAIN IN CHANNELS OF DISTRIBUTION OUTSIDE OF YOUR CONTROL.

4) THE DATE OF DISCONTINUANCE IN THE EVENT THAT YOU HAVE ALREADY DISCONTINUED MARKETING OF THIS DRUG PRODUCT.

5) YOUR INTENTION WITH RESPECT TO THE DISPOSITION OF YOUR INVENTORIES AND OUTSTANDING STOCKS IN TRADE CHANNELS.

YOUR REPLY SHOULD BE DIRECTED TO MR. RONALD G. FISCHER, DIRECTOR, COMPLIANCE BRANCH, AT THE ABOVE ADDRESS, WITH A COPY TO:

ARTHUR T. AUER, NATIONAL COORDINATOR
DRUGS AND BIOLOGICS FRAUD BRANCH (HFN-316)

00026133 00185761
REGULATORY LETTER 3/28/86 TO DOSHIRE: D.H.E.A. COMPLEX, THE FAT FIGHTER
PP: 3.

DRUG BRAND NAME(S): D.H.E.A. COMPLEX, THE FAT FIGHTER
DRUG GENERIC NAME: DEHYDROEPIANDROSTERONE, DHEA
COMPANY NAME: DOSHIRE CHICAGO, ILLINOIS
SOURCE: FOI SERVICES FULL TEXT (FT).
DOCUMENT TYPE: REGULATORY ACTION (REG).
PUBLICATION DATE: 860328

TEXT:

Mr. Donald Oppenheim
Doshire, Inc.
3441 W. Montrose
Chicago, Illinois 60613

Product: D.H.E.A. Complex, The Fat Fighter

Dear Mr. Oppenheim:

It is our information that your firm is distributing the product, D.H.E.A. Complex, The Fat Fighter. The drug label for this product states that it contains dehydroepiandrosterone (DHEA).

The ingredient, dehydroepiandrosterone (DHEA), is classed as a steroidal hormone and therefore, when intended for drug use, is regarded as a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act. Further, since this drug is not generally recognized as safe and effective for the above referenced claims or any other claims, it is a new drug within the meaning of Sections 201(p) and 505(a) of the Act.

In view of the above, the article, The Fat Fighter, as a drug, is in violation of the Federal Food, Drug and Cosmetic Act as follows:

Section 505(a): The article is a new drug which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Federal Food, Drug and Cosmetic Act, since it is a new drug within the meaning

of Section 201(p) of the Act and no approval of an application filed pursuant

to Section 505(b) is effective for such drugs, and no notice of claimed investigational exemption under Section 505(i) and Regulation 312.1 is on file for such drugs.

Section 505(f)(1): The articles are misbranded in that the labeling fails to bear adequate directions for use for the conditions for which it is offered in its promotional material and they are not exempt from this requirement under

Regulation 21 CFR 201.115 since the articles are new drugs within the meaning

of Section 201 and no approval of an application filed pursuant to Section 505(b) is effective for these articles.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of this drug product and any other applicable drug which you may market. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

We request that your reply include:

- 1) An estimate of the quantity of the drug manufactured or received within the past twelve (12) months.
- 2) An estimate of the size and frequency of shipments made by you in the past twelve (12) months.
- 3) An estimate of the amount of the drug that is in inventory under your control and of the amounts that remain in channels of distribution outside of your control.
- 4) The date of discontinuance in the event that you have already discontinued marketing this drug product.

DIVISION OF DRUG LABELING COMPLIANCE
CENTER FOR DRUGS AND BIOLOGICS
5600 FISHERS LANE
ROCKVILLE, MD 20857
SINCERELY YOURS,
RONALD M. JOHNSON
DISTRICT DIRECTOR
SAN FRANCISCO DISTRICT

1/9/58
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00026045 00185471
REGULATORY LETTERS 4/15/85 TO GENERAL NUTRITION, LIFE EXTENSION, POST-
TEL, B & R AND ATHENA: DHEA
DRUG BRAND NAME(S): DHEA
DRUG GENERIC NAME: DEHYDROEPIANDROSTERONE
COMPANY NAME: GENERAL NUTRITION PITTSBURGH, PENNSYLVANIA LIFE EXTENSION
SANTA MONICA, CALIFORNIA LIFE EXTENSION HOLLYWOOD, FLORIDA POST-TEL FORT
LAUDERDALE, FLORIDA B & R POMPANO BEACH, FLORIDA ATHENA POMPANO BEACH,
FLORIDA
SOURCE: FOI SERVICES FULL TEXT (FT)
DOCUMENT TYPE: REGULATORY ACTION (REG)
PUBLICATION DATE: 850400

TEXT:
Mr. Gary Daum, President
General Nutrition Corporation
921 Pennsylvania Avenue
Pittsburgh, Pennsylvania 15222

Re: Life Expander Fat Fighter with D.H.E.A.

Dear Mr. Daum:

It is our information that your firm is distributing/manufacturing the product "Life Expander Fat Fighter" with D.H.E.A. The label for the product states that it contains dehydroepiandrosterone (DHEA). The label for the product also states that it is useful as a "Fat/Fighter".

The ingredient, dehydroepiandrosterone (DHEA), is classed as a steroidal hormone and therefore when intended for drug use is regarded as a drug within the meaning of section 201(g) of the Federal Food, Drug and Cosmetic Act. Further, since this drug is not generally recognized as safe and effective for the above referenced claims or any other claims, it is a new drug within the meaning of section 201(p) and 505(a) of the Act.

In view of the above, the article, "Life Expander Fat Fighter with D.H.E.A.", as a drug, is in violation of the Federal Food, Drug and Cosmetic Act as follows:

Section 505(a): The article is a new drug which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Federal Food, Drug and Cosmetic Act, since it is a new drug within the meaning

of section 201(p) of the Act and no approval of an application filed pursuant

to section 505(b) is effective for such drugs, and no notice of claimed investigational exemption under section 505(i) and regulation 312.1. is on file for such drugs.

Section 502(f)(1): The article is misbranded in that the labeling fails to bear adequate directions for use for the conditions for which it is offered in its promotional material and it is not exempt from this requirement under

regulation 21 CFR 201.115 since the article is a new drug within the meaning of section 201 and no approval of an application filed pursuant to section 505(b) is effective for this article.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of this drug product and any other applicable drug which you may market. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

We request that your reply include:

- 1) An estimate of the quantity of the drug manufactured or received within the past twelve (12) months.
- 2) An estimate of the size and frequency of shipments made by you in the past twelve (12) months.
- 3) An estimate of the amount of the drug that is in inventory under your

control and of the amounts that remain in channels of distribution outside of your control.

4) The date of discontinuance in the event that you have already discontinued marketing this drug product.

5) Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Your reply should be directed to Larry E. Ormsbee, Director of Compliance Branch, with a copy to:

Arthur E. Auer, National Coordinator
Drugs and Biologics Fraud Branch (HFN-316)
Division of Drug Labeling Compliance
Office of Compliance - Center for Drugs and Biologics
5600 Fishers Lane
Rockville, Maryland 20857

Very truly yours,

Loren Y. Johnson
District Director
Philadelphia District

Saul Kent, Vice President
Life Extension Clinics, Inc.
201 Ocean Avenue
Santa Monica, California 90402

Product: DHEA Complex

Dear Mr. Kent:

It is our information that your firm is distributing the product referenced above. The label for this product states that it contains DHEA (dehydroepiandrosterone). The labeling also states that the product "...increases the rate at which food is converted into energy, rather than into body fat", "an anti-obesity and an anti-cancer agent... it may be an anti-aging agent as well", and "blocks lipogenesis (fat formulation)".

The ingredient, dehydroepiandrosterone (DHEA), is classed as a steroidal hormone and therefore when intended for drug use is regarded as a drug within the meaning of section 201(g) of the Federal Food, Drug and Cosmetic Act. Further, since this drug is not generally recognized as safe and effective for the above referenced claims or any other claims, it is a new drug within the meaning of section 201(p) and 505(a) of the Act.

In view of the above, the article DHEA Complex, as a drug, is in violation of the Federal Food, Drug and Cosmetic Act as follows:

Section 505(a): The article is a new drug which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Federal Food, Drug and Cosmetic Act, since it is a new drug within the meaning

of section 201(p) of the Act and no approval of an application filed pursuant

to section 505(b) is effective for such drugs, and no notice of claimed investigational exemption under section 505(i) and regulation 312.1 is on file for such drugs.

Section 502(f)(1): The articles are misbranded in that the labeling fails to bear adequate directions for use for the conditions for which it is offered in its promotional material and it is not exempt from this requirement under

regulation 21 CFR 201.115 since the article is a new drug within the meaning of section 201 and no approval of an application filed pursuant to section 505(b) is effective for these articles.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of this drug product and any other applicable drug which you may market. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

We request that your reply include:

1) An estimate of the quantity of the drug manufactured or received within the past twelve (12) months.

2) An estimate of the size and frequency of shipments made by you in the past twelve (12) months.

3) An estimate of the amount of the drug that is in inventory under your control and of the amounts that remain in channels of distribution outside of your control.

4) The date of discontinuance in the event that you have already

discontinued marketing this drug product.

5) Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Your reply should be directed to Martin E. Katz, Compliance Officer, Orlando District, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809,

telephone 305-855-0900, with a copy to:
Arthur E. Auer, National Coordinator
Drugs and Biologics Fraud Branch (MFN-316)
Division of Drug Labeling Compliance
Office of Compliance - Center for Drugs and Biologics
5600 Fishers Lane
Rockville, Maryland 20857

Very truly yours,

Adam J. Trujillo
District Director
Orlando District

William J. Faloon, President
Life Extension Clinics, Inc.
2835 Hollywood Boulevard
Hollywood, Florida 33022
Product: DHEA Complex

Dear Mr. Faloon:

It is our information that your firm is distributing the product referenced above. The label for this product states that it contains DHEA (dehydroepiandrosterone). The labeling also states that the product "...increases the rate at which food is converted into energy, rather than into body fat", "an anti-obesity and an anti-cancer agent... it may be an anti-aging agent as well", and "blocks lipogenesis (fat formulation)".

The ingredient, dehydroepiandrosterone (DHEA), is classed as a steroidal hormone and therefore when intended for drug use is regarded as a drug within the meaning of section 201(g) of the Federal Food, Drug and Cosmetic Act. Further, since this drug is not generally recognized as safe and effective for the above referenced claims or any other claims, it is a new drug within the meaning of section 201(p) and 505(a) of the Act.

In view of the above, the article DHEA Complex, as a drug, is in violation of the Federal Food, Drug and Cosmetic Act as follows:

Section 505(a): The article is a new drug which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Federal Food, Drug and Cosmetic Act, since it is a new drug within the meaning

of section 201(p) of the Act and no approval of an application filed pursuant

to section 505(b) is effective for such drugs, and no notice of claimed investigational exemption under section 505(i) and regulation 312.1 is on file for such drugs.

Section 502(f)(1): The articles are misbranded in that the labeling fails to bear adequate directions for use for the conditions for which it is offered in its promotional material and it is not exempt from this requirement under

regulation 21 CFR 201.115 since the article is a new drug within the meaning of section 201 and no approval of an application filed pursuant to section 505(b) is effective for these articles.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of this drug product and any other applicable drug which you may market. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

We request that your reply include:

1) An estimate of the quantity of the drug manufactured or received within the past twelve (12) months.

2) An estimate of the size and frequency of shipments made by you in the past twelve (12) months.

3) An estimate of the amount of the drug that is in inventory under your control and of the amounts that remain in channels of distribution outside of your control.

4) The date of discontinuance in the event that you have already discontinued marketing this drug product.

5) Your intention with respect to the disposition of your inventories

and outstanding stocks in trade channels.

Your reply should be directed to Martin E. Katz, Compliance Officer,
Orlando District, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida
32809,

telephone 305-855-0900, with a copy to:
Arthur E. Auer, National Coordinator
Drugs and Biologics Fraud Branch (HFN-316)
Division of Drug Labeling Compliance
Office of Compliance - Center for Drugs and Biologics
5600 Fishers Lane
Rockville, Maryland 20857

Very truly yours,

Adam J. Trujillo
District Director
Orlando District

Edward G. Astin, Jr., President
Post-Tel Services, Inc.
2946 Northwest 60th Street
Fort Lauderdale, Florida 33309

Product: Ever-Thin with Estron D

Dear Mr. Astin:

It is our information that your firm is distributing the product referenced above. The labeling for this product states that it contains DHEA (dehydroepiandrosterone). The labeling also states that the product "...helps your body fight fat", "a treatment for obesity", "can block the formation of fat", "act as an antidepressant", "causes the brain to release the hormone CCK (cholecystokinin) (and) the neurotransmitter NE (norepinephrine)", and "increase youthful vigor".

The ingredient, dehydroepiandrosterone (DHEA), is classed as a steroidal hormone and therefore when intended for drug use is regarded as a drug within the meaning of section 201(g) of the Federal Food, Drug and Cosmetic Act. Further, since this drug is not generally recognized as safe and effective for the above referenced claims or any other claims, it is a new drug within the meaning of section 201(p) and 505(a) of the Act.

In view of the above, the article Ever-Thin with Estron-D, as a drug, is in violation of the Federal Food, Drug and Cosmetic Act as follows:

Section 505(a): The article is a new drug which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Federal Food, Drug and Cosmetic Act, since it is a new drug within the meaning

of section 201(p) of the Act and no approval of an application filed pursuant

to section 505(b) is effective for such drugs, and no notice of claimed investigational exemption under section 505(i) and regulation 312.1 is on file for such drugs.

Section 502(f)(1): The articles are misbranded in that the labeling fails to bear adequate directions for use for the conditions for which it is offered in its promotional material and it is not exempt from this requirement under

regulation 21 CFR 201.115 since the article is a new drug within the meaning of section 201 and no approval of an application filed pursuant to section 505(b) is effective for these articles.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of this drug product and any other applicable drug which you may market. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

We request that your reply include:

1) An estimate of the quantity of the drug manufactured or received within the past twelve (12) months.

2) An estimate of the size and frequency of shipments made by you in the past twelve (12) months.

3) An estimate of the amount of the drug that is in inventory under your control and of the amounts that remain in channels of distribution outside of your control.

4) The date of discontinuance in the event that you have already discontinued marketing this drug product.

5) Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Your response should be directed to Martin E. Katz, Compliance Officer,
Orlando District, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida
32809,

telephone 305-855-0900, with a copy to:
Arthur E. Auer, National Coordinator
Drugs and Biologics Fraud Branch (HFV-316)
Division of Drug Labeling Compliance
Office of Compliance - Center for Drugs and Biologics
5600 Fishers Lane
Rockville, Maryland 20857

Very truly yours,

Adam J. Trujillo
District Director
Orlando District

William R. Ranne, President
B & R Shipping Co.
550-C N.E. 27th Street
Pompano Beach, Florida 33064

Product: Ever-Thin with Estron-D

Dear Mr. Ranne:

It is our information that your firm is distributing the product referenced above. The labeling for this product states that it contains DHEA (dehydroepiandrosterone). The labeling also states that the product "...helps your body fight fat", "a treatment for obesity", "can block the formation of fat", "act as an antidepressant", "causes the brain to release the hormone CCK (cholecystokinin) (and) the neurotransmitter NE (norepinephrine)", and "increase youthful vigor".

The ingredient, dehydroepiandrosterone (DHEA), is classed as a steroidal hormone and therefore when intended for drug use is regarded as a drug within the meaning of section 201(g) of the Federal Food, Drug and Cosmetic Act. Further, since this drug is not generally recognized as safe and effective for the above referenced claims or any other claims, it is a new drug within the meaning of section 201(p) and 505(a) of the Act.

In view of the above, the article Ever-Thin with Estron-D, as a drug, is in violation of the Federal Food, Drug and Cosmetic Act as follows:

Section 505(a): The article is a new drug which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Federal Food, Drug and Cosmetic Act, since it is a new drug within the meaning

of section 201(p) of the Act and no approval of an application filed pursuant to section 505(b) is effective for such drugs, and no notice of claimed investigational exemption under section 505(i) and regulation 312.1 is on file for such drugs.

Section 502(f)(1): The articles are misbranded in that the labeling fails to bear adequate directions for use for the conditions for which it is offered in its promotional material and it is not exempt from this requirement under

regulation 21 CFR 201.115 since the article is a new drug within the meaning of section 201 and no approval of an application filed pursuant to section 505(b) is effective for these articles.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of this drug product and any other applicable drug which you may market. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

We request that your reply include:

- 1) An estimate of the quantity of the drug manufactured or received within the past twelve (12) months.
- 2) An estimate of the size and frequency of shipments made by you in the past twelve (12) months.
- 3) An estimate of the amount of the drug that is in inventory under your control and of the amounts that remain in channels of distribution outside of your control.
- 4) The date of discontinuance in the event that you have already discontinued marketing this drug product.
- 5) Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Your response should be directed to Martin E. Katz, Compliance Officer,

Orlando District, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809,

telephone 305-855-0900, with a copy to:
Arthur E. Auer, National Coordinator
Drugs and Biologics Fraud Branch (HFN-316)
Division of Drug Labeling Compliance
Office of Compliance - Center for Drugs and Biologics
5600 Fishers Lane
Rockville, Maryland 20857

Very truly yours,

Adam J. Trujillo
District Director
Orlando District

Richard L. Blumberg, President
Athena Products Ltd. Company
1201 East Atlantic Boulevard
Pompano Beach, Florida 33060
Product: Ever-Thin with Estron-D

Dear Mr. Blumberg:

It is our information that your firm is distributing the product referenced above. The labeling for this product states that it contains DHEA (dehydroepiandrosterone). The labeling also states that the product "...helps your body fight fat", "a treatment for obesity", "can block the formation of fat", "act as an antidepressant", "causes the brain to release the hormone CCK (cholecystokinin) (and) the neurotransmitter NE (norepinephrine)", and "increase youthful vigor".

The ingredient, dehydroepiandrosterone (DHEA), is classed as a steroidal hormone and therefore when intended for drug use is regarded as a drug within the meaning of section 201(g) of the Federal Food, Drug and Cosmetic Act. Further, since this drug is not generally recognized as safe and effective for the above referenced claims or any other claims, it is a new drug within the meaning of section 201(p) and 505(a) of the Act.

In view of the above, the article Ever-Thin with Estron-D, as a drug, is in violation of the Federal Food, Drug and Cosmetic Act as follows:

Section 505(a): The article is a new drug which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Federal Food, Drug and Cosmetic Act, since it is a new drug within the meaning of section 201(p) of the Act and no approval of an application filed pursuant to section 505(b) is effective for such drugs, and no notice of claimed investigational exemption under section 505(i) and regulation 312.1 is on file for such drugs.

Section 502(f)(1): The articles are misbranded in that the labeling fails to bear adequate directions for use for the conditions for which it is offered in its promotional material and it is not exempt from this requirement under

regulation 21 CFR 201.115 since the article is a new drug within the meaning of section 201 and no approval of an application filed pursuant to section 505(b) is effective for these articles.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of this drug product and any other applicable drug which you may market. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

We request that your reply include:

1) An estimate of the quantity of the drug manufactured or received within the past twelve (12) months.

2) An estimate of the size and frequency of shipments made by you in the past twelve (12) months.

3) An estimate of the amount of the drug that is in inventory under your control and of the amounts that remain in channels of distribution outside of your control.

4) The date of discontinuance in the event that you have already discontinued marketing this drug product.

5) Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Your response should be directed to Martin E. Katz, Compliance Officer, Orlando District, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida

32809,
telephone 305-855-0900, with a copy to:
Arthur E. Auer, National Coordinator
Drugs and Biologics Fraud Branch (MFN-316)
Division of Drug Labeling Compliance
Office of Compliance - Center for Drugs and Biologics
5600 Fishers Lane
Rockville, Maryland 20857

Very truly yours,

Adam J. Trujillo
District Director
Orlando District

1/9/59
DIALOG(R) File 158: DIOGENES
(c) 1996 DIOGENES. All rts. reserv.

00026038 00185458
REGULATORY LETTER 4/8/85 TO PHOENIX LABORATORIES: DHEA COMPLEX TABLETS
DRUG BRAND NAME(S): DHEA COMPLEX
DRUG GENERIC NAME: DHEA. DEHYDROEPIANDROSTERONE
COMPANY NAME: PHOENIX HICKSVILLE, NEW YORK
SOURCE: FOI SERVICES FULL TEXT (FT)
DOCUMENT TYPE: REGULATORY ACTION (REG)
PUBLICATION DATE: 850408

TEXT:
Sidney Rich, President
Phoenix Laboratories, Inc.
175 Lauman Lane
Hicksville, New York 11801

Dear Mr. Rich:

It is our information that your firm is manufacturing the product DHEA Complex

Tablets, 500 mg. for various private label distributors. The labels for this product state that it contains dehydroepiandrosterone (DHEA). Promotional material associated with this product make claims in part for its use in inhibiting weight gain.

The ingredient, DHEA, is classed as a steroidal hormone and therefore is regarded as a drug within the meaning of section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Further, since this drug is not generally recognized as safe and effective for the above referenced claim or any other therapeutic claims, it is a new drug within the meaning of sections 201(p) and 505(a) of the Act.

In view of the above, the article, DHEA Complex Tablets, 500mg., as a drug, is in violation of the Act as follows:

Section 505(a): The article is a new drug which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Federal Food, Drug and Cosmetic Act, since it is a new drug within the meaning

of section 201(p) of the Act and no approval of an application filed pursuant

to section 505(b) is effective for such drug, and no notice of claimed investigational exemption under section 505(i) and regulation 21 CFR 312.1 is on file for such drug.

Section 502(f)(1): The article is misbranded in that the labeling fails to bear adequate directions for use for the conditions for which it is offered and it is not exempt from this requirement under regulation 21 CFR 201.115 since the article is a new drug within the meaning of section 201(p) and no approval of an application filed pursuant to section 505(b) is effective for this article.

We request that you reply within ten days of your receipt of this letter stating the action you will take to discontinue the marketing of this drug product. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Act provides for seizure of illegal products and injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

We request that your reply include:

1. An estimate of the quantity of the drug manufactured or received within the past 12 months.
2. An estimate of the size and frequency of shipments made by you in the past 12 months.
3. An estimate of the amount of the drug that is in inventory under your control and of the amount that remains in channels of distribution outside

of your control.

4. The date of discontinuance in the event that you have already discontinued marketing this drug product.

5. Your intention with regard to the disposition of your inventory and outstanding stock in trade channels.

Your response should be sent to Clarence L. Waltrous, Director, Compliance Branch at the above address with a copy to:

Arthur Auer, National Coordinator
Drugs and Biologics Fraud Branch, HFN-316
Division of Drug Labeling Compliance
Center for Drugs and Biologics
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

George J. Gerstenberg
District Director
Food and Drug Administration