GENELABS TECHNOLOGIES, INC.

8648 '00 DEC -5 P12:34

December 5, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Docket number 00P-1263/CP1

Dear Sir or Madam:

At FDA's request, we are submitting to the docket of our petition copies of the submissions Genelabs has previously made to the Agency regarding the regulatory status of DHEA. These consist of:

- October 6, 1996, DSHEA – DHEA Products, Request for Removal and Ban of Misbranded Dietary Supplements.
- January 28, 1997, Pre-Meeting (02/04/97) Materials - DSHEA – DHEA Products, Request for Removal and Ban of Misbranded Dietary Supplements.
- August 24, 1998, Response to the FDA's Request for Additional Information and Request to Have DHEA Dietary Supplements Removed and Banned from the Marketplace.
- April 30, 1999, Minutes of Meeting held March 31, 1999 and Data Supporting DHEA's Ability to Promote Muscle Growth.

The Agency requested these materials so that the docket would contain a complete record of Genelabs' correspondence with FDA on this issue. Once again, we reiterate our request for a quick response to our petition.

Sincerely,

Marc Gurwith, M.D.
Vice President of Drug Development and
Chief Medical Officer

Enclosures

00P-1263 SUP2

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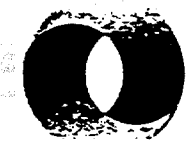
(1)



GENELABS TECHNOLOGIES, INC 8661 '00 DEC -5 P12:39

October 9, 1996

Elizabeth Yetley, Ph.D., Director
Office of Special Nutritionals,
Office of Programs
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Federal Building-8, Room 2804
HFS-450
200 C Street SW
Washington, DC 20204

RE: DSHEA - DHEA PRODUCTS
Request for Removal and Ban of
Misbranded Dietary Supplements

Dear Dr. Yetley:

Genelabs Technologies, Inc. is developing GL701, a formulation containing the new drug dehydroepiandrosterone (DHEA), for systemic lupus erythematosus (SLE) under IND No. 44,258. The Agency has approved the program for designation as an Orphan Product, under 21 CFR 316, and for expedited development, under 21 CRF 312, Subpart E. We have completed treatment for the first Phase III clinical trial of 193 patients and enrolled approximately one half of the 300 patients who will comprise the second Phase III trial; additional smaller studies have been completed, are underway, or will begin in the near future. The development plan has been presented to and accepted by the Agency and the Arthritis Advisory Committee. Thus, we have substantial interest in DHEA and are alarmed by the sale of DHEA products claiming to be dietary supplements.

DHEA has not been previously approved as a drug in the United States, although it is an approved drug in Europe and Japan. Furthermore, there is no history of its use as either a food, nutrient, dietary supplement, or herbal medicine. Reports have suggested a number of potential benefits associated with DHEA. However, there is insufficient data from controlled clinical trials or public use of DHEA with which to evaluate the risk-benefit relationship of the drug.

We ask the Agency to remove and ban from non-prescription distribution those products marketed as dietary supplements containing DHEA, since these products are misbranded as they do not meet the statutory definitions of the Dietary Supplement Heath and Safety Act of 1994 (DSHEA, Public Law 103-417) for the following reasons:

- DHEA does not meet the chemical definition for status as a dietary supplement: The Act sets forth a specific definition of dietary supplements in Section 3. Definitions, (a) Definition of Certain Foods as Dietary Supplements, (ff)(1). DHEA does not meet the criteria of clauses

(CONTINUED)

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(A), (B), (C), or (D) of the definition, since DHEA is neither a vitamin, mineral, herb or botanical, or amino acid; DHEA is a steroidal hormone that occurs in humans and other animals. DHEA does not meet the criteria for clause (E), since DHEA is not a dietary substance and thus it cannot be supplemented. There is no history of DHEA consumed as a normal food or dietary constituent in the diet of any people. DHEA is not present in plants; while commercially manufactured DHEA is produced by a multi-step chemical synthesis starting from diosgenin, a plant extract, this man-made process is artificial and does not occur in nature. DHEA is found in minute quantities in non-primate mammalian animals, principally in the adrenal gland and gonads; however, neither tissue is a usual food product and the DHEA levels in these animals are such that massive amounts of their tissues would need be consumed to approach levels that might be biochemically meaningful. DHEA does not meet the criteria for clause (F), since DHEA cannot be concentrated, metabolized, extracted or otherwise naturally derived from materials defined in clauses (A), (B), (C), (D), or (E). This argument is elaborated in APPENDIX A.

- DHEA does not qualify for regulatory status as a dietary supplement: The Act states the inclusionary criteria in Section 3. Definitions, (a) Definition of Certain Foods as Dietary Supplements, (ff)(3)(B)(ii). DHEA fails to meet these criteria since it has been authorized for investigation as a new drug, for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public prior to enactment of DSHEA. In addition, DHEA has not been previously authorized for marketing as a dietary supplement or as a food. In fact, the Agency has previously acted to ban the distribution of DHEA as a dietary supplement. This argument is elaborated in APPENDIX B.

We conclude that DHEA does not meet either the statutory chemical or regulatory requirements for distribution as a dietary supplement under DSHEA. Furthermore, we contend that DHEA-containing products are contrary to the intent of the Act which, we believe, is to allow minimally restricted public access to nutritional and botanical products for which there is implicit safety and reasonably foreseeable benefit based on a history of the product's use as a food or a traditional ethnic herbal medicine.

Therefore, we respectfully ask that the Agency take immediate action to stop the illegal distribution and sale of these DHEA products that are misbranded as dietary supplements, as well as those DHEA products that carry no labeling whatsoever; a listing of DHEA products which we have identified to date is presented as APPENDIX C.

Sincerely,

Robert M. Cohen
Senior Director of Regulatory Affairs

Submitted: Original and 2 copies to CFSAN; Desk copy to Dr. Yetley; Requested copies to W. Schultz; M. Weintraub, B. Williams CDER; 3 copies to IND No. 44,258, Serial No. 037
Sent: Express Mail on October 9, 1996 to above (202) 205-4168
Reference: 44,258.037//100996.701.037/CFSAN/FDA

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APPENDIX A

DHEA Does Not Meet The Chemical Definition For Status As A Dietary Supplement

The Dietary Supplement Heath and Safety Act of 1994 (DSHEA, Public Law 103-417) sets forth a specific definition of dietary supplements: "The term 'dietary supplement' means a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract or, combination of any ingredient described in clause (A), (B), (C), (D), or (E)." [Sec. 3. Definitions, (a) Definition of Certain Foods as Dietary Supplements, (ff)(1)]

DHEA fails to meet these criteria due to the following facts:

- DHEA does not meet the criteria of clauses (A), (B), (C), or (D) of the definition, since DHEA is neither a vitamin, mineral, herb or botanical, or amino acid; DHEA is a steroidal hormone that occurs in animals. The following information is provided as reference:

  "DHEA (dehydroepiandrosterone, Prasterone, 3-Hydroandrost-5-en-17-one): CAS No. 7710, Chem. Abstracts Reg. No. 53-43-0, Therapeutic Category: Androgen." The *Merck Index, An Encyclopedia of Chemical, Drugs, and Biologicals* (1)

  "Prasterone (Note: Prasterone is pseudonym for DHEA) is a naturally occurring, but relatively weak, androgen. Pharmacopoeias: Japan includes Prasterone Sodium Sulfate. Proprietary Names, Multi-ingredient Preparations: Gynodian, Gynodian Depot. *Martindale, The Extra Pharmacopoeia* (2)

- DHEA does not meet the criteria for clause (E) of the definition, since DHEA is not a dietary substance and thus it cannot be supplemented. There is no history of DHEA consumed as a normal food or dietary constituent in the diet of any people. DHEA is not present in plants; while some commercially manufactured DHEA is produced by a multi-step chemical synthesis starting from diosgenin, a plant extract, this man-made process is artificial and does not occur in nature. DHEA is found in minute quantities in non-primate mammalian animals, principally in the adrenal gland and gonads; however, neither tissue is a usual food product and the DHEA levels in these organs are such that massive amounts of these tissues would need be consumed to approach levels that might be biochemically meaningful. The following information is provided as reference:

(CONTINUED)

"Diet : 1. Food and drink regularly provided or consumed. 2. Habitual nourishment. 3. The kind and amount of food prescribed for a person or animal for special reasons." *Webster's Medical Desk Dictionary* (3)

"It is highly improbable that DHEA itself or any other steroidal nutrient that may theoretically serve as a precursor for DHEA, is present in our diet in amounts which, when ingested in the course of normal eating customs, will produce the biological effects associated with endogenously-produced DHEA" according to Dr. Seymour Lieberman, the acknowledged expert in DHEA biochemistry. (APPENDIX A, Exhibit 1). (4)

- DHEA does not meet the criteria for clause (F) of the definition, since DHEA cannot be concentrated, metabolized, extracted or otherwise naturally derived from materials defined in clauses (A), (B), (C), (D), or (E).

APPENDIX A

Exhibit 1

Position Paper

"Are Nutrients a Source of DHEA"

Seymour Lieberman, Ph.D.

President,, The St. Luke's-Roosevelt Institute for Health Sciences and Professor Emeritus of Biochemistry

Columbia University
New York, NY

October 3, 1996

A POSITION PAPER
ARE NUTRIENTS A SOURCE OF DHEA?

Seymour Lieberman, Ph.D.

October 3, 1996

October 3, 1996

ST. LUKE'S-ROOSEVELT
A University Hospital of Columbia University
College of Physicians & Surgeons

Seymour Lieberman, Ph.D.
President
Institute for Health Sciences

INTRODUCTION

Dehydroepiandrosterone (DHEA), a compound that is normally produced in adrenal glands of mammals including humans, is being consumed by large numbers of people presumably because it can alleviate the symptoms of many afflictions. Claims have been made that the ingestion of DHEA is beneficial in the treatment of a large array of diabilities ranging from cancer and aging to abnormal behavior. The compound is easily procured since it is now being sold over the counter.

The claims have also been made that DHEA, since it is a naturally occurring substance, may be a constituent of foodstuffs. Moreover the possibility has been advanced that some constituents of our diets may, under normal digestive conditions, be converted into DHEA.

This paper addresses two issues: (I) Is dehydroepiandrosterone (DHEA) a steroid normally secreted by endocrine glands (adrenals, testes and ovary) of mammals, a constituent of the food we eat? Is it ever present in food in the form and amount so that it can mimic the physiological action(s) that is evoked by the endogenous secretion of DHEA by the endocrine glands? The second issue (II) is: are there other steroidal constituents of our diet that can be converted by the normal metabolic processes of our bodies into a form and into amounts that would mimic the physiologic action(s) expressed by DHEA endogenously secreted by endocrine glands?

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METHODS

To obtain information about Issue I, a search of the literature from 1937-1996 was made (DHEA was first discovered in 1935). A search was made for any citation that indicated that DHEA was a constituent of any plant, edible or not. Two sources were consulted: 1) Chemical Abstracts from 1937-1965 and 2) Medline from 1966 to August 1996. The subject headings used for this search are listed on the accompanying computer print-outs.

RESULTS AND DISCUSSION

The results from the Medline search are also shown in these print-outs. The bottom digit in the right hand column indicates the number of citations uncovered by combining files 7 and 8. The abstracts of each of the 79 citations (see Table 1) were displayed on the monitor and examined. None reported that DHEA was present in an extract of a plant.

Likewise the search conducted by examining the entries in Chemical Abstracts from 1937-1965 failed to uncover any reference to the occurrence of DHEA in plants.

Moreover two excellent reviews of plant steroids written by Eric Heftmann were consulted (1,2). They report that many steroids occur in plants and that these as well as exogenously added steroids are extensively metabolized by enzymes present in some plants. Of greater relevance, however, is the fact that these reviews confirm that there are no reports that DHEA occurs in plants. Nor do they present evidence that DHEA is the metabolic end-product of steroids (or sterols) that are endogenously present in plants. Thus it may be concluded that it is highly improbable that DHEA itself or any other steroidal nutrient that may theoretically serve as a precursor of DHEA, is present in our diet in amounts which, when ingested in the course of normal eating customs, will produce the biological effects associated with endogenously-produced DHEA.

The second issue (II): Are there foodstuffs that can be converted into DHEA by metabolic reactions occurring normally in tissues of the body? can be analyzed as follows: Dietary

cholesterol is obviously the principal contender for such a foodstuff since this compound is generally accepted as the remote sterolic precursor of that DHEA which is made in the endocrine glands of mammals. It would be difficult to determine what fraction of the cholesterol ingested as a constituent of some food (meat, eggs, lobster etc) is converted into DHEA. At least 50% of the cholesterol, taken by mouth, is eliminated from consideration since it is excreted into the feces without ever entering the blood. The dietary cholesterol that enters the plasma does reach the endocrine glands where DHEA is fabricated but steroidogenic cells in these glands also can biosynthesize cholesterol de novo from acetate. As a result it is difficult to determine how much blood-borne cholesterol contributes to DHEA production and how much is derived from cholesterol made de novo in endocrine glands from low molecular weight precursors like acetate. The important point is that only if the blood concentration of cholesterol is an important factor in determining the production rate of DHEA in the adrenal (or testes or ovary) will that rate be influenced by the amount of cholesterol ingested in the food. Obviously many other factors (e.g. the concentrations of the steroidogeneic enzymes, P450scc, $P450_{17}$, levels of pituitary trophic factors (ACTH, LH, FSH etc) as well as hypothalamic hormones (CRF, LH-RF etc)) may regulate DHEA secretion. Considering the roles of these other factors, it is unlikely that the concentration of blood-borne cholesterol is a significant limiting factor in regulating this process.

Support for this assertion can be gleaned from the following considerations: If plasma levels of cholesterol were an important determinant of DHEA produced, then the plasma levels of both compounds, cholesterol and DHEA, should run parallel, i.e. when cholesterol levels are high, the levels of DHEA should also be high. Thus, people with hypercholesteremia should have high levels of plasma DHEA (free or as sulfate). But the available evidence reveals that this coincidence does not prevail. The available evidence shows that hypercholesterolemic patients do not have elevated plasma levels of DHEA or DHEAS.

Moreover if plasma cholesterol levels are reduced by drug treatment, then DHEAS levels should also at the same time be lowered, (if the two compounds rise and fall in parallel). However DHEA levels do not fall when plasma cholesterol levels are lowered. In 1986 Boizel et al (3) had reported that patients with homozygous familial hypercholesterolemia had abnormally low DHEAS levels (65-80) compared to controls (200 ug/dl). Stimulation with ACTH evoked an impaired response in DHEAS levels compared to controls. ACTH increased DHEAS levels but the serum cholesterol levels were unchanged, clearly showing that the control of DHEA secretion was not solely, if at all, dependent upon blood cholesterol levels.

In 1989 Mol et al (4) reported that administration of simvastatin, a derivative of lovastatin and a potent inhibitor of cholesterol synthesis, to 24 patients with severe primary hypercholesterolemia reduced cholesterol levels by 35% without altering DHEAS levels significantly.

In 1991 Jay et al (5) lowered total blood cholesterol levels as well as LDL cholesterol with two drugs (Pravastatin and Cholestyramine; each given to 12 patients) and found "no significant difference in plasma DHEAS levels between treatment and control groups".

Similar results were obtained 1992 by Kjaer et al (6) using a different drug, Simvastatin, in 10 hypercholesterolemic patients with Type I diabetes. The administration of the drug lowered the cholesterol level without affecting the concentration of plasma DHEAS.

Another line of evidence came from Averna et al (6) in 1993, who determined the DHEAS levels in the cord blood of babies born with transient neonatal hypercholesterolemia. The DHEAS levels did not differ significantly from those of babies with normal cholesterol levels.

Three other recent reports (8,9,10) add to the evidence already cited above indicating that an elevated blood level of cholesterol is not associated with concurrently elevated levels of DHEA or its sulfate. Finally and perhaps most

convincingly is the well known fact that during the normal process of aging plasma cholesterol levels rise and DHEA levels decline. Thus the existing data indicate that blood-borne cholesterol is not an important factor in determining the production rate of DHEA by endocrine glands.

CONCLUSION

It is highly improbable that constituents of our diet, which enter into the blood,(among which is cholesterol, the most likely contender as a precursor of DHEA) are converted to DHEA by the enzymes present in the tissues of the body. The factors influencing the production of DHEA are numerous (e.g. status of the steroid producing endocrine glands (e.g., hyperplasia, cancer, etc) and the status of the pituitary (ACTH, LH & FSH) and hypothalamus (CRF) etc but these factors do not include any known dietary nutrient. As far as is known now, no foodstuff can mimic the physiological or pharmacological consequences evoked by DHEA, endogenously secreted or exogenously administered.

REFERENCES

1. Heftmann, Erich, - Lipids 9:626-39, 1974
2. Heftmann, Erich, - Lloydia 38:195-209, 1975
3. Boizel, R; de Peretti, E; Cathiard, AM; Halimi, S; Bost, M; Berthezene, F; Saez JM - Clinical Endocrinology 25:363-371 1986.
4. Mol, MJTM; Stalenhoef, AFH; Stuyt, PMJ; Hermus, ARMM; Demacker, PNM; Van'T Laar, A. - Clinical Endocrinology 31:679-689, 1989
5. Jay, RH; Sturley, RH; Stirling, C; McGarrigle, HHG; Katz, M; Reckless, JPD; Betteridge, DJ - J. Clin. Pharmac. 32: 417-422, 1991
6. Kjaer, K; Hangaard, J; Petersen, NE; Hagen, Claus - Acta Endocrinological 126:229-32, 1992.
7. Averna, MR; Barbagallo, LM; DiPaola, G; LaPlaca, PP; Scatidi, V; Dimita, U; Notarbartolo, A - Hormone & Metabolic Res. 25:271-4, 1993.
8. Dobs, AS; Sarma, PS; Schteingart, D - Metabolism 42: 1146-1152, 1993.
9. Barrett-Connor, E; Goodman-Gruen, D - Annals of the N.Y. Academy of Sciences 4:259-70, 1995.
10. Hautanen, A; Manttari, M; Manninen, V; Adlercreutz, H. - J. Steroid Biochem. Molec. Biol. 51:307-313, 1995.

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2	dhea.tw.	407
3	prasterone/	726
4	exp plants/	22842
5	nutrients.tw.	2024
6	food.tw.	136/4
7	1 or 2 or 3	1104
8	4 or 5 or 6	3/111
9	7 and 8	34

Ovid - Medline <1992 to August 1996>

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_:

Author Textword | Journal Database | Limit Set View Set | Combine Sets Print Set | Save Exit

File Edit Search Limit View Tools Database Options Help

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6	food.tw.	17446
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8	4 or 5 or 6	41287
9	7 and 8	31

Ovid - Medline <1986 to 1991>

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File Edit Search Limit View Tools Database Options Help

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4	exp plants/	18423
5	nutrients.tw.	1537
6	food.tw.	11918
7	1 or 2 or 3	1229
8	4 or 5 or 6	30788
9	7 and 8	10

Ovid - Medline <1980 to 1985>

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File Edit Search Limit View Tools Database Options Help

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3	prasterone/	569
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8	4 or 5 or 6	20330
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10	4 and 7	0

Ovid - Medline (1976 to 1979)

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Author Journal Limit Set Combine Sets Save

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6	food.tw.	6262
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8	4 or 5 or 6	46021
9	7 and 8	4

Ovid - Medline <1966 to 1975>

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Enter subject, then press <Enter>
_:

SEYMOUR LIEBERMAN

BORN: December 1, 1916

BUSINESS ADDRESS: St. Luke's-Roosevelt Institute for Health Sciences,
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RESIDENCE: 515 E. 72 Street (30H) New York, NY 10021

EDUCATION:

B.S.	Brooklyn College	1936
M.S.	University of Illinois	1937
Ph.D.	Stanford University	1941

FELLOWSHIPS:

Rockefeller Research Fellow, Stanford University	1939-41
Special Research Associate, Harvard University	1941-45
Traveling Fellow, University of Basle and Eidgenoess. Tech. Hochschule, Zurich, Switzerland	1946-47

POSITIONS:

Special Research Associate, Memorial Hospital	1941-46
Associate Member, Sloan Kettering Institute	1946-50
Assistant Professor Biochemistry, Columbia University	1950-52
Associate Professor Biochemistry, Columbia University	1952-62
Professor of Biochemistry, Columbia University	1962-87
Professor Emeritus of Biochemistry, Columbia Univ.	1987-
Program Officer, Ford Foundation	1974-75
President, The St. Luke's-Roosevelt Institute for Health Sciences	1981-
Associate Dean, College of Physicians & Surgeons, Columbia University	1985-90
Vice Provost, Columbia University	1988
Associate Director, Office of Science & Technology (CIE)	1991-

COMMITTEES:

Panel on Steroids, Committee on Growth	1945-49
Panel on Hormones, Committee on Growth	1949-50
Panel on Endocrinology, Committee on Growth	1955-56
Advisory Committee on Research on the Etiology of Cancer, American Cancer Society	1957-60
Editorial Board, Journal of Clinical Endocrinology and Metabolism	1958-63 1968-70
Associate Editor, Journal of Clinical Endocrinology and Metabolism	1963-67
Endocrinology Panel, Cancer Chemotherapy, National	

Cancer Service	1958-62
Medical Advisory Committee, Population Council	1961-71
Endocrinology Study Section, Division of Research Grants, National Institutes of Health	1959-63
Chairman, Endocrinology Study Section, Division of Research Grants, National Institutes of Health	1963-65
General Research Centers Committee National Institutes of Health	1967-71
Consultant, World Health Organization, Human Reproduction Unit	1972-74
Membership Committee, American Society of Biological Chemists	1964-66
Editorial Board, Journal of Biological Chemistry	1975-80
Subcommittee on Health Applications of Radioactive Materials, Dept. of Health, City of New York	1963-74
U.S. Delegate to Central Committee on International Society of Endocrinology, 3 Terms	1964-76
Chairman, Advisory Research Committee, Ford Foundation	1975-77
Program Committee, International Congress on Hormonal Steroids: 2nd Congress (1966); 3rd Congress (1970); 4th Congress (1974)	
Endocrine Society:	
Vice President	1967-68
Member of Council	1970-73
President	1974-75
Ciba Award (Endocrine Society)	1952
Pfizer Traveling Fellow, McGill University	1968
Syntex Lecturer, Mexican Endocrine Society	1970
Koch Award (Endocrine Society)	1970
Distinguished Alumnus Award, Brooklyn College	1971
Fellow, New York Academy of Sciences	1977
Member, National Academy of Sciences	1977
Honorary President, Sixth International Congress on Hormonal Steroids	1982
Roussel Prize	1984
Dale Medal, Society for Endocrinology, United Kingdom	1986
Distinguished Service Award, College of Physicians & Surgeons, Columbia University	1991
Boehringer Mannheim Award Lecturer, The Association of Clinical Biochemists, United Kingdom	1992
Visiting Professor at the Universities of Indiana, Massachusetts, Nebraska, Ohio State, South Carolina, Vanderbilt, Wisconsin	

APPENDIX B

DHEA Does Not Qualify For Regulatory Status As A Dietary Supplement

The Dietary Supplement Heath and Safety Act of 1994 (DSHEA, Public Law 103-417) states the definition: "The term 'dietary supplement' means a product that does not include an article authorized for investigation as a new drug, antibiotic, or biologic 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 unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding the article would be lawful under the act. " [Sec. 3. Definitions, (a) Definition of Certain Foods as Dietary Supplements, (ff)(3)(B)(ii)]

DHEA fails to meet these criteria due to the following circumstances:

- DHEA has been authorized for investigation as a new drug, for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. The following information is provided as reference:

  Genelabs Technologies filed an Investigational New Drug (IND) application on December 22, 1993 for GL701 (DHEA for SLE), to which the Agency assigned IND No. 44,258 on January 6, 1994.

  Clinical investigation of DHEA under the IND began on May 10, 1994 as study GL94-01. Approximately 25% of the GL94-01 study patients were enrolled and treated at the time DSHEA was enacted (October 25, 1994). The existence and initiation of the study was publicly announced in a press release issued on May 10, 1994. (Exhibit 1) *(5)*

  Prior clinical investigation had begun as Phase I and II studies, conducted by Stanford University under IND No. 37,873 and exclusively licensed to Genelabs. The existence of the studies and their license to Genelabs were publicly announced in a press release issued on November 11, 1993. (Exhibit 2) *(6)* Additionally, the existence of these trials was publicized as a presentation at the 1994 Annual Meeting of the American College of Rheumatology, as well as prior publication in major scientific journals. *(7-13)*

(CONTINUED)

- DHEA has not been previously authorized for marketing as a dietary supplement or as a food. In fact, the Agency has previously acted to ban the distribution of DHEA as a dietary supplement. The following information is provided as reference:

  FDA announced on April 9, 1985 that it was "instructing manufacturers and distributors of the drug DHEA...to discontinue selling...the steroidal hormone DHEA...because it is an unapproved new drug...for which the risks of long-term use are unknown." (Exhibit 3) *(14)*

  FDA Regulatory Letters and Recall Actions to various manufacturers and distributors in 1985 and 1986 so instructed the discontinuation of the sale of DHEA products, with reference to its distribution as a dietary supplement and the Agency determination that it is an unapproved new drug. (Exhibit 4) *(15-26)*

- The Secretary has not issued or proposed a regulation finding that DHEA would be lawful under the act.

APPENDIX B

Exhibit 1

Press Release

"Genelabs Begins Phase II/III New Drug Trial for Lupus "

Genelabs Technologies, Inc.
Redwood City, CA

May 10, 1994

GENELABS TECHNOLOGIES, INC.

NEWS RELEASE

CONTACT:

Andrea A. Boscoe
Genelabs Technologies, Inc.
415-369-9592 ext. 303

Mark Brand
Pondel Parsons & Wilkinson
310-207-9300

FOR IMMEDIATE RELEASE

GENELABS BEGINS PHASE II/III NEW DRUG TRIAL FOR LUPUS

Redwood City, California—May 10, 1994— Genelabs Technologies, Inc. (Nasdaq: GNLB) today announced the start of a randomized, double-blind, placebo controlled, multi-center, Phase II/III clinical trial of GL701-DHEA (dehydroepiandrosterone) for the treatment of mild to moderate systemic lupus erythematosus (SLE, lupus) in women who require prednisone or other steroids for their treatment. GL701 is one of three drugs in clinical trials for Genelabs.

Lupus is a chronic, autoimmune disease of unknown cause that damages the kidneys, nervous system, skin, joints, and linings of the lungs, heart and other organs. Lupus occurs predominantly in young women.

Current therapy for lupus consists mainly of prednisone, the use of which is associated with significant adverse effects including premature osteoporosis, atherosclerosis, psychosis and increased incidence of infection due to immunosuppression.

"Based on earlier studies performed at Stanford University Medical Center, we believe that GL701 is a potential product which may improve the quality of life for lupus patients through reduction of prednisone usage," said Irene Chow, Ph.D. president of Genelabs' biopharmaceutical division.

Established in 1984, Genelabs Technologies, Inc. is a global biopharmaceutical and diagnostic company. Genelabs is developing therapeutic and vaccine products for viral diseases, autoimmune disorders and other life-threatening or debilitating conditions, and is developing and marketing a portfolio of viral diagnostic products. Genelabs has 220 employees in facilities located in Redwood City, California; San Antonio, Texas; Morris Plains, New Jersey; Geneva, Switzerland; Leuven, Belgium; Taiwan, ROC; and Singapore.

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505 Penobscot Drive Redwood City, California 94063 Tel 415.369.9500 Fax 415.365.2709

APPENDIX B

Exhibit 2

Press Release

" Genelabs Technologies, Inc. Licenses Promising Lupus Therapy"

Genelabs Technologies, Inc.
Redwood City, CA

November 11, 1993

GENELABS TECHNOLOGIES, INC.

NEWS RELEASE

CONTACT:

Irene Chow, Ph.D.
Genelabs Technologies, Inc.
415-369-9500

Andrea A. Boscoe
Genelabs Technologies, Inc.
415-369-9592 ext. 303

Mark Brand
Pondel Parson & Wilkinson
310-207-9300

FOR IMMEDIATE RELEASE

GENELABS TECHNOLOGIES, INC. LICENSES PROMISING LUPUS THERAPY

STANFORD UNIVERSITY SCIENTIST REPORTS PHASE II FINDINGS AT SCIENCE CONFERENCE

Redwood City, California – November 11, 1993 – Genelabs Technologies, Inc. (NASDAQ: GNLB) today announced the signing of an exclusive licensing agreement with Stanford University of Stanford, California for the development of dehydroepiandrosterone (DHEA), a drug for the treatment of Systemic Lupus Erythematosus (SLE, lupus).

Under the terms of agreement, Genelabs receives exclusive worldwide marketing and sublicensing rights to Stanford's DHEA patent and clinical results while Stanford receives milestone and royalty payments based on future clinical development goals and sales figures. Genelabs assumes management of the drug's future development and, upon regulatory approval, will market DHEA worldwide.

The agreement was announced in conjunction with a presentation by Ronald van Vollenhoven, M.D., Ph.D., senior fellow in the division rheumatology of Stanford University's School of Medicine of the results of a double-blind, randomized, placebo-controlled Phase II study testing DHEA in lupus patients. Dr. van Vollenhoven's results were presented at the 57th Annual meeting of the American College of Rheumatology in San Antonio, Texas. In addition to Dr. van Vollenhoven, principal investigators include James L. McGuire, M.D., associate professor of medicine and chief of staff of Stanford University Hospital and Edgar Engleman, M.D., professor of pathology and medicine for Stanford University.

- more -

505 Penobscot Drive Redwood City, California 94063 Tel 415.369.9500 Fax 415.365.0709

The study involved 30 patients with mild to moderate lupus. Randomized patients received either DHEA or placebo daily over a three month study period. Patients were evaluated against four parameters: patient self-assessment, physician assessment, systemic lupus erythematosus disease activity index (SLEDAI) and dose of prednisone, a drug commonly used to treat lupus.

Whereas the placebo treated patients failed to improve during the study, the DHEA treated patients showed improvement in all four parameters. The results supported earlier, open-label studies by the Stanford group, which suggested that DHEA treatment is beneficial in lupus.

"We believe that these results indicate that DHEA is a potentially effective drug treatment against lupus," said Irene Chow, Ph.D., president of Genelabs' pharmaceutical division. Moreover, the licensing of DHEA significantly strengthens our product pipeline," Chow noted.

DHEA, a naturally occurring hormone produced by the adrenal glands, is known to be present in abnormally low levels in lupus patients. Previous studies have suggested that hormonal influences played a key role in the development and progression of the disease. The precise mechanism responsible for the therapeutic effect of DHEA remains to be determined.

"We have been particular impressed with the tolerability of DHEA in woman with lupus," said James L. McGuire, M.D., associate professor of medicine and chief of staff of Stanford University Hospital. "Although our experience is limited with DHEA, patients showed a consistent improvement in all parameters studied," Dr. McGuire added.

Lupus, which affects an estimated 135,000 Americans, is a chronic, autoimmune, inflammatory disease, that affects the skin, joints, kidneys, nervous system, and serous membranes lining the lungs, heart, and abdominal cavity. Lupus is 3-4 times more common in women than men.

Genelabs Technologies, Inc. is a human healthcare products company utilizing proprietary technologies to address the global need to diagnose, prevent and treat infectious diseases and cancer. Genelabs has 215 employees in facilities located in Redwood City, California; San Antonio, Texas; Geneva, Switzerland; Leuvan, Belgium; Taiwan, ROC; and Singapore.

# # #

APPENDIX B

Exhibit 3

Press Release

"DHEA an Unapproved New Drug That Requires Premarket Approval"

HHS News; FDA No. P85-12
U.S. Food and Drug Administration
Rockville, MD

April 9, 1985

SENT BY:Xerox Telecopier 7020 ; 5- 6-93 ; 3:09PM ; 3012358119→(919) 361-2280 ;# 2

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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APPENDIX B

Exhibit 4

Regulatory Action/Letters and Drug Recall Announcements (Multiple regarding DHEA products).

U.S. Food and Drug Administration
Rockville, MD

MEMORANDUM

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

DCLC
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.W.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 (HFN-313) 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
AEAuer:zah:2/12/85:2/20/85:3/10/85:3/27/85
R/D Init: AJAronson:3/26/85

039ZH

1/9/63
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00022877 00101242
PRESS RELEASE 4/9/85: DHEA AN UNAPRROVED 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 effectiviness.

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 estabilished 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 fradulent 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 agains 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 agains 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
P.O. Box 1111
Mount Vernon, NY 10553

The May CR presented on 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 obove 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

1/9/60
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00023532 00102077
MICHIGAN PHARMACAL CLASS III RECALL 7/29/85: D.H.E.A. COMPLEX TABLETS.
FDA NO.: D-432-5
DRUG BRAND NAME(S): D.H.E.A. COMPLEX TABLETS
COMPANY NAME: J W S DELAVAU PHILADELPHIA, PENNSYLVANIA MICHIGAN PHARMACAL FERNDALE, MICHIGAN
SOURCE: FDA ENFORCEMENT REPORT 8/21/85.
DOCUMENT TYPE: REGULATORY ACTION (REG). Drug Recall
PUBLICATION DATE: 850729
TEXT:
Michigan Pharmacal Corportation, Ferndale, Michigan initiated an ongoing recall on July 29, 1985 regarding D.H.E.A. Complex Tablets, sold under the Vibrant Life and Vibrant Health labels as a natural diet supplement, in bottles of 50. The tablets manufactured by J.W.S. Delavau Company, Philadelphia, Pennsylvania is a new drug marketed without an approved New Drug Application. FDA estimates 200-300 bottles remain on the market from the distribution in the following states: Michigan, Indiana, Ohio, Illinois, New York, Florida, Georgia, Missouri, Kansas, Texas, Arizona, Nevada, Washington state and California.

1/9/61
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00023200 00101605
GENERAL NUTRITION CLASS III RECALL 4/12/85: LIFE EXPANDER FAT FIGHTER WITH DHEA.
FDA NO.: D-409-5
DRUG BRAND NAME(S): LIFE EXPANDER
DRUG GENERIC NAME: DEHYDROEPIANDROSTERONE. DHEA
COMPANY NAME: GENERAL NUTRITION GREENVILLE, SOUTH CAROLINA PITTSBURG, PENNSYLVANIA
SOURCE: FDA ENFORCEMENT REPORT 6/12/85.
DOCUMENT TYPE: REGULATORY ACTION (REG). Drug Recall
PUBLICATION DATE: 850412
TEXT:
General Nutrition Corporation, Pittsburg, Pennsylvania initiated ongoing recall on April 12, 1985 regarding Life Expander brand Fat Fighter with DHEA (dehydroepiandrosterone) 500mg. tablets, in 50 and 100 tablet bottles manufactured by General Nutrition Corporation, Greenville, South Carolina. The product is a new drug marketed without approved New Drug Application and lacks adequate directions for use. The firm estimates that none of the product remains on the market from the nationwide distribution.

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
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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 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 OD CLAIMED INVESTIGATIONAL EXEMPTION UNDER SECTION 505(i) AMD 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
DIALOG(R)File 158:DIOGENES
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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) ABD 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) AMD 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
DIALOG(R)File 158:DIOGENES
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00026047 00185479
REGULATORY LETTER 5/9/85 TO VITAMIN RESEARCH: DHEA 1%
DRUG BRAND NAME(S): DHEA 1%
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 1%
DEAR MS. CHANG:

IT IS OUR INFORMATION THAT YOUR FIRM IS MANUFACTURING AND OR DISTRIBUTING THE PRODUCT DHEA 1%. 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 1%, 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) AMD 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, dehyroepiandrosterone (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, dehyroepiandrosterone (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

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, dehyroepiandrosterone (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, dehyroepiandrosterone (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

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, dehyroepiandrosterone (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, dehyroepiandrosterone (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

1/9/59
DIALOG(R)File 158:DIOGENES
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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

APPENDIX C

List Of DHEA Products Sold As "Dietary Supplements"

Company	Product	Comment
Amerfit; Bloomfield, CT	Stack 6	
Bifina L.L.C. (Deepak's Natural Remedies); Novato, CA	Deepak's Timed Release DHEA	Not labeled Dietary Supplement
Bio Research Institute, Division of Bondtech-Klebrig Corp.; Lake Mary, FL	DHEA	Not labeled Dietary Supplement
Body Amino USA/International; Hayward, CA	DHEA	
Country Life; Hauppauge, NY	DHEA 25 mg	Not labeled Dietary Supplement
Ciena International; Reno, NV	Vita DHEA	DHEA not a labeled ingredient Not labeled Dietary Supplement
Diamond Enterprises; Lakewood, CO	DHEA	Not labeled Dietary Supplement
Futurebiotics; Hauppauge, NY	DHEA	
Genesis Nutrition	DHEA	
Genetic Evolutionary Nutrition; Los Angeles, CA	DHEA	Not labeled Dietary Supplement
Global Pharmaceuticals, Inc.; Manchester, NH	DHEA	
Great Earth Companies, Inc.; Los Angeles, CA	Metacurb DHEA 25	
Jarrow Formulas Inc; Los Angeles, CA	DHEA-25	
Labrada Nutritional Systems, Inc; Houston, TX	DHEA	
Life Enhancement Products, Inc.; Petaluma, CA	DHEA & DHEA ThermoPlex	Not labeled Dietary Supplement
LifeLink; Grover Beach, CA	DHEA Ultra Tech	Not labeled Dietary Supplement
Natrol, Inc.; Charsworth, CA	DHEA 25 mg	
Nature's Heritage; Los Angeles, CA	DHEA 5 mg	Not labeled Dietary Supplement
Nature's Plus, Division of Natural Organics, Inc.; Melville, NY	DHEA	
Nutraceutics Corporation; Deerfield Beach, FL	DHEA Plus	DHEA not a labeled ingredient Not labeled Dietary Supplement
Optimal Nutrients; Foster City, CA	Opti-DHEA	Not labeled Dietary Supplement
Premier Labs; San Diego, CA	DHEA 50 mg	Not labeled Dietary Supplement
So Cal Sports Supplements; San Diego	DHEA	
Solaray, Inc.; Ogden, UT	Mexican Yam Extract & Adrenal Gland Concentrate	
Taney Marketing; Mountain View, CA	DHEA Max	Not labeled Dietary Supplement
Tools for Exploration; San Rafael, CA	DHEA	
Vital Source	DHEA	Not labeled Dietary Supplement

APPENDIX D

References

(1) *The Merck Index, An Encyclopedia of Chemical, Drugs, and Biologicals.* Eleventh Edition; Merck & Co., Rahway, NJ; 1989; S. Budavari, editor; pages 1221 and Ther-7

(2) *Martindale, The Extra Pharmacopoeia.* Thirtieth Edition; The Pharmaceutical Press, London; 1993; J.E.F. Reynolds, editor; Chapter: Sex Hormones, Chapter: Sex Hormones, Page 1194

(3) *Webster's Medical Desk Dictionary.* Merriam-Webster Inc., Springfield, MA; 1986; page 180

(4) *Personal Correspondence* Seymour Lieberman, Ph.D., Columbia University, New York, NY. October 3, 1996 (Appendix A)

(5) *Press Release: Genelabs Begins Phase II/III New Drug Trial for Lupus*. Genelabs Technologies, Inc., Redwood City, CA; May 10, 1994 (Appendix B)

(6) *Press Release: Genelabs Technologies, Inc. Licenses Promising Lupus Therapy.* Genelabs Technologies, Inc., Redwood City, CA; November 11, 1993 (Appendix C)

(7) *Treatment Of Systemic Lupus Erythematosus With Dehydroepiandrosterone. Interim Analysis Of A Double-Blinded, Randomized, Placebo Controlled, Clinical Trial.* van Vollenhoven RF, Engleman EG, Lambert RE, Lee YSL, and McGuire JL Arthritis Rheum, 36: S92, 1993.

(8) *Treatment Of Systemic Lupus Erythematosus With Dehydroepiandrosterone. Follow-Up From An Open-Label Clinical Trial.* van Vollenhoven RF, Lambert RE, Lee YSL, McGuire JL, and Engleman EG. Arthritis Rheum, 36: S228, 1993.

(9) *Treatment Of SLE With DHEA-A Pilot Study.* van Vollenhoven RF, Lee YSL, Lambert RE, Engleman EG, McDevitt HO, and McGuire JL. Arthritis Rheum, 35: S55, 1992.

(10) *An Open Study Of Dehydroepiandrosterone In Systemic Lupus Erythematosus.* van Vollenhoven RF, Engleman EG, and McGuire JL. Arthritis Rheum, 37: 1305-10. 1994.

(11) *In Patients With Systemic Lupus Erythematosus, Treatment With Dehydroepiandrosterone Restores Abnormally Low In Vitro Production of IL-2, IL-6 and TNF-α.* van Vollenhoven RF, Morales A, Yen S, Hochfeld MB, Morabito LM, Engleman EG, and McDevitt HO. Abstract from 58th Annual Scientific Meeting of the American College of Rheumatology. 1994.

(12) *Treatment Of Systemic Lupus Erythematosus With Dehydroepiandrosterone. Follow-Up Data From A Double-Blinded, Randomized, Placebo Controlled, Clinical Trial..* van Vollenhoven RF, Morabito LM, Lambert RE, Lee YSL, Engleman EG, and McGuire JL. Abstract from 58th Annual Scientific Meeting of the American College of Rheumatology. 1994.

(13) *Treatment Of Systemic Lupus Erythematosus With Dehydroepiandrosterone. Two Year Follow-Up From An Open-Label Clinical Trial.* van Vollenhoven RF, Morabito LM, Engleman EG, Lambert RE, Lee YSL, and McGuire JL. Arthritis Rheum, 37: S369, 1994.

(14) *Press Release: DHEA an Unapproved New Drug That Requires Premarket Approval.* U.S. Food and Drug Administration, HHS News; Rockville, MD; FDA No. P85-12; April 9, 1985 (Appendix D)

(15) *Regulatory Action/Letter to Phoenix Laboratories, Inc. 4/8/85: DHEA Complex Tablets.* U.S. Food and Drug Administration; Rockville, MD; April 8, 1985 (Appendix E)

(16) *Regulatory Action/Drug Recall: General Nutrition Class III Recall 4/12/85: Life Expander Fat Fighter With DHEA.* FDA Enforcement Reports. U.S. Food and Drug Administration; Rockville, MD; FDA No. D-409-5; June 12, 1985 (Appendix E)

(17) *Regulatory Action/Letter to General Nutrition 4/15/85: Life Expander Fat Fighter.* U.S. Food and Drug Administration; Rockville, MD; April 15, 1985 (Appendix E)

(18) *Regulatory Action/Letter to Athena Products 4/15/85: Ever-Thin With Estron-D.* U.S. Food and Drug Administration; Rockville, MD; April 15, 1985 (Appendix E)

(19) *Regulatory Action/Letter to B&R Shipping Company 4/15/85: Ever-Thin With Estron-D.* U.S. Food and Drug Administration; Rockville, MD; April 15, 1985 (Appendix E)

(20) *Regulatory Action/Letter to Life Extension Clinics, Inc. 4/15/85: DHEA Complex.* U.S. Food and Drug Administration; Rockville, MD; April 15, 1985 (Appendix E)

(21) *Regulatory Action/Letter to Post-Tel Services, Inc. 4/15/85: Ever-Thin With Estron-D.* U.S. Food and Drug Administration; Rockville, MD; April 15, 1985 (Appendix E)

(22) *Regulatory Action/Letter to Barth Vitamin 4/24/85: DHEA Complex Tablets.* U.S. Food and Drug Administration; Rockville, MD; April 24, 1985 (Appendix E)

(23) *Regulatory Action/Letter to Bedford Vitamin 4/24/85: DHEA Complex.* U.S. Food and Drug Administration; Rockville, MD; April 24, 1985 (Appendix E)

(24) *Regulatory Action/Letter to Vitamin Research Products 5/9/85: : D.H.E.A. Complex, The Fat Fighter.* U.S. Food and Drug Administration; Rockville, MD; May 9, 1985 (Appendix E)

(25) *Regulatory Action/Drug Recall: Michigan Pharmacal Class III Recall 7/29/85: D.H.E.A. Complex Tablets.* FDA Enforcement Reports. U.S. Food and Drug Administration; Rockville, MD; FDA No. D-432-5; August 21, 1985 (Appendix E)

(26) *Regulatory Action/Letter to Doshire, Inc. 3/28/86: DHEA 1%.* U.S. Food and Drug Administration; Rockville, MD; March 28, 1986 (Appendix E)

(2)

8659 '00 DEC -5 P12:39

GENELABS TECHNOLOGIES, INC.

DSHEA - DHEA Products
Request for Removal and Band of
Misbranded Dietary Supplements
- pre-Meeting (020497) Materials

Tel. 415.369.9500
505 Penobscot Drive Redwood City, California 94063
Fax 415.368.0709

GENELABS TECHNOLOGIES, INC.

January 28, 1997

Elizabeth Yetley, Ph.D., Director
Office of Special Nutritionals, Office of Programs
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Federal Building-8, Room 2804
HFS-450
200 C Street SW
Washington, DC 20204

RE: DSHEA - DHEA PRODUCTS
Request for Removal and Ban of
Misbranded Dietary Supplements
- Pre-Meeting (020497) Materials

Dear Dr. Yetley:

Thank you for the opportunity to meet with you and your colleagues at CFSAN offices on Tuesday, February 4, 1997 from 2:00 until 3:00 p.m. At this meeting, we wish to discuss the status of our submission of October 9, 1996, which requests the Agency take action to remove and ban from non-prescription distribution those products marketed as dietary supplements containing DHEA (dehydroepiandrosterone).

Accompanying this cover letter are a proposed Agenda and a list of meeting participants. Also included are pre-meeting materials, including drafts of the anticipated presentation slides.

We look forward to a fruitful discussion of this important problem.

Sincerely,

Robert M. Cohen
Senior Director of Regulatory Affairs
and Corporate Administration

Submitted:
- Original and 2 copies to CFSAN; Desk Copies to Meeting Attendees (E. Yetley, P. Binzer, J. Latham, R. Moore, B. Lake, B. Williams, I. Bernsetin, P. Derfler; R. Cohen, K. Schwartz)
- Desk Copies to W. Schultz (OC); J. Woodcock, M. Lumpkin, R. Williams, M. Weintraub, (CDER); M. Haffner (Office of Orphan Products), R. Merkatz (Office of Women's Health)
- Copies (3) to IND No. 44,258, Seriai 041;Desk Copies: W. Chambers, K. Johnson, L. LoBianco (OAAODP, ODEV, CDER)
- Desk Copies to I. Chow, J. Smith, D. Bannister, M. Grifith (GLT), W. Vodra (AP)

Sent: January 28, 1997 - Express Mail to above (202) 205-4168; Telefacsimile (Pages 1 through 5 only) to (202) 205-5295
Reference: 44,258.041//012897.701.041/Yetley/FDA(DHEA-DS/DSHEA)

Tel 415.369.9500
505 Penobscot Drive Redwood City, California 94063
Fax 415.368.0709

DSHEA - DHEA PRODUCTS
Request Removal and Ban of Misbranded Dietary Supplements

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