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APR 18 1975

CLERK, U.S. DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

BY DEPUTY

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8 UNITED STATES DISTRICT COURT
9 GENERAL DISTRICT OF CALIFORNIA

11 UNITED STATES OF AMERICA,
12 Plaintiff,
13 v.
14 GENERAL RESEARCH LABORATORIES,
15 INC., a corporation, et al.,
16 Defendants.

No. CV 73-2917-MML

PROPOSED FINDINGS OF FACT
AND CONCLUSIONS OF LAW

17
18 This cause having come on for trial on Tuesday, April
19 22, 1975, the plaintiff appearing by its attorneys William D.
20 Keller, United States Attorney, Frederick M. Brosio, Jr.,
21 Assistant U. S. Attorney, Chief of Civil Division, by Dzintra
22 I. Janavs, Assistant U. S. Attorney, and defendants appearing
23 by their attorney Stephen Tornay, the Court having considered
24 all of the evidence presented and admitted, having read the
25 written briefs filed, having heard the oral argument of counsel,
26 being fully advised, makes the following:

27 FINDINGS OF FACT

28 1. This is an action filed by the United States of
29 America, pursuant to the provisions of the Federal Food, Drug
30 and Cosmetic Act, 21 U.S.C. 332(a), seeking to enjoin defendants
31 from shipping the articles "(picture of Bee) Seventeen" (here-
32 after B17) and "Aprikern" in interstate commerce or holding them

13:tw

1 for sale after shipment in interstate commerce.

2 2. The defendant, General Research Laboratories, is
3 a corporation organized and existing under the laws of the State
4 of California and trading and doing business at 6925 Hayvenhurst
5 Avenue, Van Nuys, California, within the jurisdiction of this
6 Court.

7 3. The defendant, Alex S. Geczy, an individual, is
8 the president of said corporation and performs his duties as
9 such at 6925 Hayvenhurst Avenue, Van Nuys, California, within
10 the jurisdiction of this Court.

11 4. The defendant, Nancy L. Geczy, an individual, is
12 the vice president of said corporation and performs her duties
13 as such at 6925 Hayvenhurst Avenue, Van Nuys, California,
14 within the jurisdiction of this Court.

15 5. The defendant, Donald I. Kuehne, an individual,
16 is the secretary of said corporation and performs his duties
17 as such at 6925 Hayvenhurst Avenue, Van Nuys, California,
18 within the jurisdiction of this Court.

19 6. The defendant, Institute of Nutritional Research
20 is a corporation organized and existing under the laws of the
21 State of California and trading and doing business, within the
22 jurisdiction of this Court.

23 7. The defendant, Emory W. Thurston, Ph.D., Sc.D.,
24 an individual, is an official of said Institute of Nutritional
25 Research and nutrition consultant to General Research Labora-
26 tories and performs his duties, within the jurisdiction of this
27 Court.

28 8. The articles B17 and Aprikern are distributed
29 in interstate commerce and manufactured from ingredients shipped
30 in interstate commerce.

31 9. The articles B17 and Aprikern are used for food
for man.

1 10. The article B17 consists of several vitamins
2 and minerals, miscellaneous nutrients, and 500 mg. of amygdalin
3 in a base of apricot fruit and kernel concentrate.

4 11. The article Aprikern consists of a one gram
5 gelatin capsule containing four ground and defatted apricot
6 kernels.

7 12. The label for the article B17 states that it
8 is a food for special dietary use.

9 13. The label for the article B17, by stating that
10 the food is a food for special dietary use, and listing the
11 apricot fruit and kernel concentrate containing 500 mg. of
12 amygdalin along with the sixteen vitamins and minerals, repre-
13 sents and suggests that the apricot fruit and kernel concentrate
14 containing 500 mg. of amygdalin is a nutrient with special
15 dietary properties.

16 14. Apricot fruit and kernel concentrate containing
17 500 mg. of amygdalin is not a nutrient with special dietary
18 properties.

19 15. The logogram "(picture of a Bee) Seventeen" on
20 the label of the article B17 represents to the consumer that
21 the product is or contains Vitamin B17, and that Vitamin B17
22 is a vitamin recognized in human nutrition and a vitamin of
23 the B complex.

24 16. "Vitamin B17" is also commonly known as amygdalin
25 and laetrile.

26 17. There is no Vitamin B17 that is a recognized
27 vitamin in human nutrition.

28 18. There is no vitamin of the B complex that is
29 recognized in human nutrition as Vitamin B17.

30 19. The article Aprikern contains hydrogen cyanide
31 in the amount of 1.5 mg. to 2.7 mg. per gram of ground and
32 defatted apricot kernel and 1.09 mg. to 1.60 mg. hydrogen

1 cyanide per capsule of aprikern.

2 20. When hydrogen cyanide is present in the human
3 body at a rate greater than the body's ability to detoxify the
4 hydrogen cyanide, cyanide poisoning, manifested by labored
5 breathing, vomiting, ataxia, convulsions and death occurs.

6 21. Acute oral toxicity tests conducted by the
7 University of Arizona Department of Pharmacology and Toxicology
8 determined the minimum lethal dose of Aprikern (50% of or more
9 of the subject animals died) to be 2g/kg of body weight in rats.
10 These tests determined that Aprikern administered at the rate
11 of 1g/kg of body weight caused symptoms of cyanide poisoning,
12 including labored breathing and convulsions, without death.
13 Control group animals showed no effects.

14 22. Acute oral toxicity tests conducted by the FDA
15 established a minimum lethal dose of Aprikern at the rate of
16 2.5g/kg of body weight. At a level of 1.9 and 2.2g/kg of body
17 weight, the subject animals showed signs of cyanide poisoning,
18 including labored breathing, convulsions and death. At a rate
19 2.8, 3.1 and 3.4g of Aprikern per kg of body weight, all animals
20 died.

21 23. Acute oral toxicity tests of Aprikern in beagle
22 dogs conducted by the FDA revealed vomiting and convulsions
23 when Aprikern was administered at a rate of 1.5g/kg body weight
24 via stomach tube, vomiting and convulsions occurred; when
25 administered at a rate of 2.2g/kg body weight in meat, vomiting
26 occurred; when administered in capsule form at a rate of 2.5g/
27 kg body weight, vomiting and convulsions occurred.

28 24. Acute toxicity tests of Aprikern in monkeys
29 conducted by the FDA revealed vomiting, labored breathing and
30 malaise when capsules were fed at a rate of 1.2 and 1.3g/kg of
31 body weight; when administered by gavage at a rate of 2.4g/kg
32 body weight, vomiting, convulsions and death occurred; when

1 administered at a rate of 1.4g/kg body weight, labored breathing
2 and vomiting occurred.

3 25. The lethal dose of hydrogen cyanide in human
4 beings ranges between 50 and 280 mg for an 80 kg person.

5 26. Due to its hydrogen cyanide content, Aprikern
6 is unfit for food.

7 27. Amygdalin is present in both of the articles
8 B17 and Aprikern.

9 28. The presence of the substance amygdalin in
10 ground and defatted apricot kernels and apricot kernel con-
11 centrate in both B17 and Aprikern results in its becoming a
12 component of the said articles of food.

13 29. Amygdalin is not generally recognized by experts
14 qualified by scientific training and experience to evaluate
15 its safety, as having been shown through scientific procedures,
16 including original animal, analytical and other scientific
17 studies and on an unprejudiced compilation of both favorable
18 and unfavorable reliable information drawn from the scientific
19 literature, to be safe under the conditions of its use in the
20 articles B17 and Aprikern.

21 30. There is no regulation in effect permitting
22 the use of amygdalin in foods as a food additive or exempting
23 amygdalin from the food additive requirements of the Federal
24 Food, Drug and Cosmetic Act.

25 31. Vitamin B17, also known as amygdalin and laetrile
26 are used in the treatment, prevention, cure and mitigation of
27 cancer in man.

28 32. Said substance is an unproven or unorthodox
29 cancer remedy.

30 33. The danger in the use of such remedies by public
31 and specifically cancer victims is in their delaying or foregoing
32 diagnosis and treatment which is generally recognized by the

1 medical profession as beneficial and effective.

2 34. The defendants and their agents have sold and pro-
3 moted B17 and Aprikern at International Association of Cancer
4 Victims and Friends and Cancer Control Society Conventions and
5 other conventions where unorthodox methods on cancer prevention
6 and treatment have been significant topics of lectures and speeches

7 ~~35. At these conventions speakers have displayed B17~~
8 in connection with speeches concerning benefits of laetrile, also
9 known as amygdalin, and Vitamin B17 in cancer cure and prevention.

10 36. Literature by defendant Thurston, published by
11 the Thurston Division of General Research Laboratories, speaks
12 of the benefits of laetrile also known as amygdalin and Vitamin
13 B17 in treating of cancer.

14 37. One item of such literature also contains a
15 picture of defendant Thurston standing next to Dr. Dean Burk
16 in front of a sign "~~General Research Laboratories~~". The caption
17 states: "Dr. Dean Burk, Chief Cytologist at the National Cancer
18 Institute . . . is an interested observer while Emory Thurston
19 samples the new 'breakfast drink' Seventeen (first demonstrated
20 at the convention in Los Angeles in July)."

21 38. Defendants and their agents have represented
22 B17 and Aprikern to be the same as and/or similar to laetrile.

23 39. Defendants have represented B17 and Aprikern
24 to be used in the treatment, prevention, cure and mitigation
25 of cancer.

26 40. Defendants intend the articles B17 and Aprikern
27 to be used in the treatment, prevention, cure and mitigation of
28 cancer in man.

29 41. The labels for the articles B17 and Aprikern fail
30 to bear any warnings or directions for use or other information
31 connected with its use, including dosage, duration and frequency
32 of administration.



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APR 25 1975

CLERK, U.S. DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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Sec. Reg. (re: memo)*

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UNITED STATES DISTRICT COURT
 CENTRAL DISTRICT OF CALIFORNIA

APR 25 1975

CLERK, U.S. DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

11 UNITED STATES OF AMERICA,)
 12 Plaintiff,)
 13 v.)
 14 GENERAL RESEARCH LABORATORIES,)
 15 a corporation, INSTITUTE OF)
 16 NUTRITIONAL RESEARCH, a corpora-)
 17 tion and ALEX S. GECZY, NANCY L.)
 18 GECZY, DONALD J. KUENENE, and)
 19 EMORY W. THURSTON, Ph.D., Sc.D.,)
 20 individuals,)
 21 Defendants.)

No. CV 73-2917-MML

PERMANENT INJUNCTION

20 This cause having come on for trial on April 22, 23
 21 and 24, 1975, the plaintiff appearing by its attorneys William
 22 D. Keller, United States Attorney, Frederick M. Brosio, Jr.,
 23 Assistant U. S. Attorney, Chief of Civil Division, by Dzintra
 24 I. Janavs, Assistant U. S. Attorney, and Jay H. Geller, Attorney,
 25 Food and Drug Administration, and defendants appearing by their
 26 attorney Stephen Tornay, the Court having considered all of the
 27 evidence presented and admitted, and the written and oral
 28 arguments of counsel, being fully advised, in accordance with
 29 Findings of Fact and Conclusions of Law signed herein, it
 30 appearing that the defendants have violated and may continue to
 31 violate the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 331(a),
 32 and 331(k), unless restrained by order of this Court by doing

1 or causing to be done the following acts with respect to articles
2 of food and drug, namely "[bee] Seventeen," and "Aprikern" or
3 similar articles of food and drug:

4 (a) introducing or delivering for introduction into
5 interstate commerce said articles of food and drug which are
6 adulterated or misbranded within the meaning of 21 U.S.C. 342(a)
7 (2)(C), 342(a)(3), 343(a), 352(f)(1) and 352(f)(2); and

8 (b) manufacturing, processing, packing, and labeling
9 articles of food and drug, while said articles are held for sale
10 after shipment of one or more of their components in interstate
11 commerce, which acts result in said articles being adulterated
12 or misbranded within the meaning of 21 U.S.C. 342(a)(2)(C),
13 342(a)(3), 343(a), 352(f)(1) and 352(f)(2);

14 IT IS THEREFORE ORDERED that the plaintiff's prayer
15 for a permanent injunction be and is hereby granted;

16 IT IS FURTHER ORDERED that the defendants, General
17 Research Laboratories, a corporation, Institute of Nutritional
18 Research, a corporation, and Alex S. Geczy, Nancy L. Geczy,
19 Donald J. Kuehne, and Emory W. Thurston, Ph.D., Sc.D., individuals,
20 and each and all of their officers, agents, servants, employees,
21 representatives, and any and all persons in active concert or
22 participation with them be restrained and enjoined from directly
23 or indirectly doing or causing to be done any of the following
24 acts with respect to articles of food and drug known as "[bee]
25 Seventeen," and "Aprikern," or any similar articles of food and
26 drug;

27 I. Introducing or delivering for introduction into
28 interstate commerce any of said articles of food and drug,

29 (a) which bear or contain the food additive,
30 amygdalin, which is unsafe within the meaning of 21 U.S.C. 348(a)
31 since said additive and its use and intended use is not in con-
32 formity with a regulation or exemption in effect pursuant to

1 21 U.S.C. 348;

2 (b) which are unfit for food by reason of the
3 potential for release of hydrogen cyanide from said food;

4 (c) which bear or are accompanied by labeling which
5 represents and suggests that apricot fruit and kernel concentrate
6 containing amygdalin is a nutrient with special dietary properties,
7 or that there is a Vitamin B17 that is a recognized nutrient
8 essential to human nutrition, or that there is a Vitamin B17
9 that is a member of the B complex family of vitamins;

10 (d) which bear or are accompanied by labeling that
11 fails to bear adequate directions for use because

12 (1) the labeling fails to state the purpose
13 or condition for which the articles are intended,
14 namely, for the treatment or prevention of cancer, or

15 (2) in the event the labeling declares the
16 articles' intended purpose and condition, namely,
17 for the treatment or prevention of cancer, the
18 label must bear directions for use as required by
19 the Federal Food, Drug and Cosmetic Act.

20 (e) which bear or are accompanied by labeling that
21 fails to bear adequate warnings against use in those pathological
22 conditions and by children where their use may be dangerous to
23 health, and against unsafe dosage and methods and duration of
24 administration or application, in such manner and form, as are
25 necessary for the protection of users;

26 II. Manufacturing, processing, packing, or labeling
27 any of said articles of food and drug or similar articles of
28 food and drug while held for sale after shipment of one or more
29 of their components in interstate commerce, which acts of
30 manufacturing, processing, packing and labeling result in said
31 articles,

32 (a) bearing or containing the food additive,

1 amygdalin, which is unsafe within the meaning of 21 U.S.C. 348(a)
2 since said additive and its use and intended use is not in con-
3 formity with a regulation or exemption in effect pursuant to
4 21 U.S.C. 348;

5 (b) being unfit for food by reason of the potential
6 for release of hydrogen cyanide from said food;

7 (c) bearing or being accompanied by labeling which
8 represents or suggests that apricot fruit and kernel concentrate
9 containing amygdalin is a nutrient with special dietary pro-
10 perties; or that there is a Vitamin B17 that is a recognized
11 nutrient essential to human nutrition, or that there is a Vitamin
12 B17 that is a member of the B complex family of vitamins;

13 (d) bearing or being accompanied by labeling that
14 fails to bear adequate directions for use because

15 (1) the labeling fails to state the purpose
16 or condition for which the articles are intended,
17 namely, for the treatment or prevention of cancer, or

18 (2) in the event the labeling declares the
19 articles' intended purpose and condition, namely,
20 for the treatment or prevention of cancer, the
21 label must bear directions for use as required
22 by the Federal Food, Drug and Cosmetic Act.

23 (e) bearing or being accompanied by labeling that
24 fails to bear adequate warnings against use in those pathological
25 conditions and by children where their use may be dangerous to
26 health, and against unsafe dosage and methods and duration of

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1 administration or application, in such manner and form, as are
2 necessary for the protection of users.

3 Issued this _____ day of April, 1975.

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MALCOLM M. LUCAS
UNITED STATES DISTRICT JUDGE

Presented by:

DZINTRA I. JANAVS
DZINTRA I. JANAVS
Assistant U. S. Attorney