

**DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE
HAD BEEN ISSUED**

4583. P. B. S. C. drug and Anti-Bacterial Root Canal Cement. (F. D. C. No. 33776. S. Nos. 91-830 K, 23-140 L, 23-485 L.)

INFORMATION FILED: 7-9-53, S. Dist. N. Y., against Sultan's Pharmacy, Inc., New York, N. Y., and John O. Cramer, president.

SHIPPED: *P. B. S. C. drug* on 11-20-50 and *Anti-Bacterial Root Canal Cement* on 1-7-52 and 2-12-52, from New York to New Jersey.

LABEL IN PART: (Box) "P. B. S. C." and "Cohen-Luks Anti-Bacterial Root Canal Cement Contains: Aureomycin, Silver, Rosin ZnO, with a Balsamic-Eucalyptus Comp."

CHARGE: *P. B. S. C. drug.* 502 (e) (2)—when shipped its label bore no statement of the active ingredients; and, 502 (1)—it was a drug composed in part of penicillin, and it was not from a batch with respect to which a certificate or a release had been issued pursuant to the law.

Anti-Bacterial Root Canal Cement (1-7-52 shipment). 501 (c)—its strength differed from that which it was represented to possess since it did not contain aureomycin as represented; and, 502 (a)—the label statement "Contains aureomycin" was false and misleading.

Anti-Bacterial Root Canal Cement (2-12-52 shipment). 502 (1)—it was represented as a drug composed partly of aureomycin, and it was not from a batch with respect to which a certificate or a release had been issued pursuant to the law.

P. B. S. C. drug and both shipments of *Anti-Bacterial Root Canal Cement.* 502 (b) (2)—the labels of the drugs bore no statement of the quantity of contents.

PLEA: Guilty by corporation to all 4 counts of information and by Cramer to 3 counts relating to *Anti-Bacterial Root Canal Cement.*

DISPOSITION: 2-10-55. Corporation fined \$400; Cramer given sentence of 6 months in jail, which was suspended, and placed on probation for 6 months.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR
ADEQUATE DIRECTIONS OR WARNING STATEMENTS***

4584. Lipitrons capsules and Super Lipitrons capsules. (F. D. C. No. 33791. S. Nos. 14-755 L, 15-706 L, 30-995 L.)

INFORMATION FILED: 8-6-53, Dist. Nebr., against Vitamin Industries, Inc., Omaha, Nebr., and Joseph L. Zweiback, president.

SHIPPED: Between 8-3-51 and 1-11-52, from Omaha, Nebr., to Peoria, Ill., and Topeka, Kans.

CHARGE: The articles were charged to be misbranded under 502 (a) and 502 (f) (1). The nature of such charges is set forth in the court's opinion quoted below.

PLEA: Not guilty.

DISPOSITION: The case was tried before the court without a jury on 2-22-54, and on 3-31-55, the court handed down the following memorandum opinion and decision in which the defendants were found guilty and fined:

*See also No. 4581.

DELEHANT, *District Judge*: "By information in three counts, the plaintiff charges the defendants with the violation of Title 21 U. S. C. A., Sections 331 and 333. The nature of the charge under Count I may be gathered from a copy of that count which is set out in a footnote.¹ Count II differs from Count

¹ "The United States Attorney charges :

"That Vitamin Industries, Inc., a corporation organized and existing under the laws of the State of Nebraska and trading and doing business at 1511 Davenport Street, Omaha, State of Nebraska, and Joseph L. Zweiback, an individual, at the time hereinafter mentioned president of said corporation, the defendants herein, did, within the Omaha Division of the District of Nebraska, within the period from on or about August 3, 1951, to on or about August 6, 1951, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Omaha, State of Nebraska, for delivery to Topeka, State of Kansas, consigned to the Jayhawk Drug Co., a number of bottles containing a drug ;

"That displayed upon said bottles was certain labeling which consisted, among other things, of the following printed and graphic matter :

Guardian 100 Caplets Lipitrons	
High Potency Lipotropic Formula	
Each Caplet Contains :	
Vitamin B ₁ -----	15 mgm.
Vitamin B ₂ -----	6 mgm.
Vitamin C-----	50 mgm.
Niacinamide-----	30 mgm.
Calcium Pantothenate-----	3 mgm.
Vitamin B ₆ -----	0.5 mgm.
Desiccated Whole Liver-----	175 mgm.
Dried Debittered Yeast-----	175 mgm.
Choline Dihydrogen Citrate-----	20 mgm.
Inositol-----	20 mgm.
dl-Methionine-----	20 mgm.
Iron as Ferrous Gluconate-----	30 mgm.
Folic Acid-----	0.1 mgm.
Vitamin B ₁₂ (oral conc.)-----	3 mgm.

"That accompanying said drug was certain additional labeling relating to said drug, namely, a poster entitled 'If you are over 35 If You Are Getting That Growing Old Feeling * * * A True Geriatric Formula Designed Especially For Advanced Age Groups To Help You Enjoy Life Again * * *';

"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was misbranded within the meaning of 21 U. S. C. 352 (a) 20 mgm. Inositol 20 mgm. dl-Methionine 20 mgm., which appeared on the bottle label, was false and misleading in that said statement represented and suggested that said drug possessed significant lipotropic properties ; whereas, said drug did not possess significant lipotropic properties ;

"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (a) in that the statement 'Each Caplet Contains * * * Choline Dihydrogen Citrate 20 mgm. Inositol 20 mgm. dl-Methionine 20 mgm.,' which appeared on the bottle label, was misleading in that said statement represented, suggested, and created the impression that said drug, when used as directed, would provide significant amounts of Choline dihydrogen citrate, inositol, and dl-methionine ; whereas, said drug, when used as directed, would not provide significant amounts of choline dihydrogen citrate, inositol, and dl-methionine ;

"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (a) in that the aforesaid additional labeling of said drug contained the following statements, to wit :

If you are over 35 If You Are Getting That Growing Old Feeling A True Geriatric Formula Designed Especially For Advanced Age Groups To Help You Enjoy Life Again * * *

which statements were false and misleading in that said statements when read in the light of the newspaper advertisements for said drug which appeared in the Topeka State Journal for August 6, 1951, and in the Topeka Daily Capital newspaper for August 7, 1951, represented, suggested, and created the impression that said drug was effective in the treatment of persons more than 35 years old suffering from a growing old feeling, tiredness, weakness, and run-down condition, and that it was effective to help recapture lost vitality and strength ; to combat nervousness and lack of vigor and energy ; to help one to really begin to enjoy life again ; and to attack true basic causes of the tired feeling, poor appetite, loss of weight and strength, insomnia or sleeplessness, and other symptomatic conditions of deficiencies in nutritional intake ; whereas, said drug was not effective in the treatment of persons more than 35 years old suffering from a growing old feeling, tiredness, weakness, and run-down condition ; and was not effective to help recapture lost vitality and strength ; to combat nervousness and lack of vigor and energy ; to help one to really begin to enjoy life again ; or to attack true basic causes of the tired feeling, poor appetite, loss of weight and strength, insomnia or sleeplessness, or other symptomatic conditions of deficiencies in nutritional intake ;

"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (f) (1) in that the labeling of said drug failed to bear adequate directions for use for the purposes and conditions for which it was intended, namely, for the treatment of persons over 35 years old suffering from a growing old feeling, tiredness, weakness, and run-down condition ; to help recapture lost vitality and strength ; to combat nervousness

I only in these respects: (a) It charges shipment between September 20, 1951, and October 4, 1951; (b) It alleges that the labeling displayed upon the bottles also 'accompanied' the bottles; (c) It alleges that the statement quoted in the fifth paragraph of footnote 1, supra, was both false and misleading; and (d) It alleges newspaper advertising in the September 24, 1951, issue of Topeka State Journal and the September 25, 1951, issue of Topeka Daily Capital. Count III, though similar to Count I, differs in this, that it alleges: a) a single shipment on or about January 11, 1952, to Peoria, Illinois, consigned to Peoria Health Food Center, of a number of bottles, containing a drug, b) upon which bottles was labeling consisting, among other things, of the following language:

Guardian 100 Capsules
Super Lipitrons
Vitamin B₁₂ High Potency
B Complex with Iron & Vitamin C
Each Capsule Contains:

Vitamin B ₁	15 mgm.
Vitamin B ₂	6 mgm.
Vitamin C.....	50 mgm.
Niacinamide.....	30 mgm.
Calcium Pantothenate.....	3 mgm.
Liver Concentrate.....	30 mgm.
Vitamin B ₆	0.5 mgm.
Choline Dihydrogen Citrate.....	20 mgm.
Inositol.....	20 mgm.
dl-Methionine.....	20 mgm.
Iron as Ferrous Gluconate.....	30 mgm.
Folic Acid USP.....	0.1 mgm.
Vitamin B ₁₂ (Crystalline).....	3 mcg.

and, c) newspaper advertising in the January 22, 1952, issue of Peoria Journal, and d) falsity and misbranding of the drug specified in respects and particulars as set out in a footnote.²

and lack of vigor and energy; to help one to really begin to enjoy life again, and to attack true basic causes of the tired feeling, poor appetite, loss of weight and strength, insomnia or sleeplessness, and other symptomatic conditions of deficiencies in nutritional intake, which are the purposes and conditions for which said drug was offered in the newspaper advertisements appearing in the August 6, 1951, issue of the Topeka State Journal and the August 7, 1951, issue of the Topeka Daily Capital newspaper, which newspaper advertisements were sponsored by and on behalf of said defendants.

"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (a) in that the statement 'Each Capsule Contains * * * Choline Dihydrogen Citrate 20 mgm. Inositol 20 mgm. dl-Methionine 20 mgm.' which appeared on the bottle label, was misleading in that said statement represented, suggested, and created the impression that said drug, when used as directed, would provide significant amounts of choline dihydrogen citrate, inositol, and dl-methionine, whereas, said drug, when used as directed, would not provide significant amounts of choline, dihydrogen citrate, inositol, and dl-methionine."

²"That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (a) in that the aforesaid additional labeling of said drug contained the following statements, to wit:

If You Are Over 35 If You Are Getting That "Growing Old" Feeling * * * A True
Geriatric Formula Designed Especially For Advanced Age Groups To Help You
Enjoy Life Again * * *

which statements were false and misleading in that said statements, when read in the light of the newspaper advertisements for said drug, which appeared in the Peoria Journal for January 22, 1952, represented, suggested and created the impression that said drug was effective in the treatment of persons over 35 years old to combat that feeling of growing old; to relieve those suffering from tiredness, weakness, nervousness, and run-down condition; to overcome the deficiencies that help drag one down; for premature advancing age; to furnish a whole new world of buoyant energy, vitality and strength by relieving and overcoming the basic causes of their nutritional deficiencies; to help those who feel years older than their age to enjoy life again; to regain vigor and vibrant energy; and to enable thousands of men and women to work harder, and to cause the difference between their old listless dragged-out feeling and new vitality; whereas, said drug was not effective in the treatment of persons over 35 years old to combat that growing old feeling; to relieve those suffering from tiredness, weakness, nervousness, and run-down condition; to overcome the deficiencies that help drag one down; for premature advancing age; to furnish a whole new world of buoyant energy, vitality and strength by relieving and overcoming the basic causes of their nutritional deficiencies; to help those who feel years older than their age to enjoy life again; to regain vigor and

"Each defendant pleaded not guilty as to each count of the information. Trial by jury was waived and the case was tried before the court without a jury. Much of the evidence was received under a stipulation. That is especially true in respect of the business relationship of the defendants, the making of the alleged shipments, the contents of the labels upon the bottles and the shipment of some advertising material in the way of posters, and the publication of newspaper advertising. Both the government and the defendants supplemented the stipulation with oral testimony and also with exhibits beyond those introduced in association with the stipulation.

"The facts are now found by the court. They may be considered to have been stipulated except to the extent that they are declared to be the court's findings upon unstipulated evidence.

"Of the defendants, Vitamin Industries, Inc., at all material times was, and still is, a corporation duly organized and existing under the laws of Nebraska, with its principal place of business in Omaha, Nebraska, and Joseph L. Zweiback at all such times was and is its principal stockholder and accountable manager.

"Shortly prior to August 10, 1951, the defendants within the Omaha Division of this District introduced and caused to be introduced for shipment in interstate commerce from Omaha, Nebraska, to Topeka, Kansas, consigned to Jayhawk Drug Company at Topeka, Kansas, a number of bottles, each containing a drug bearing the label of, and in part identifying the contents as, 'Guardian Lipitrons.' Affixed to and displayed upon each of said bottles was a label containing the following printed and graphic material:

Guardian 100 Caplets Lipitrons High Potency
Lipotropic Formula Each Caplet Contains:

Vitamin B ₁	15 mgm.
Vitamin B ₂	6 mgm.
Vitamin C.....	50 mgm.
Niacinamide.....	30 mgm.
Calcium Pantothenate.....	3 mgm.
Vitamin B ₆	0.5 mgm.
Desiccated Whole Liver.....	175 mgm.
Dried Debittered Yeast.....	175 mgm.
Choline Dihydrogen Citrate.....	20 mgm.
Inositol.....	20 mgm.
dl-Methionine.....	20 mgm.
Iron as Ferrous Gluconate.....	30 mgm.
Folic Acid.....	0.1 mgm.
Vitamin B ₁₂ (Oral conc.).....	3 mgm.

The same label also contained the following language:

A DIETARY SUPPLEMENT

DIRECTIONS: Adults—One capsule per day or as directed by the physician. Each Capsule supplies the following ration of the minimum adult daily requirements: 1500% of Vitamin B₁, 300% of Vitamin B₂, 167% of Vitamin C, and 33% of Iron. The daily adult requirement for Niacina-

vibrant energy; and to enable thousands of men and women to work harder, and to cause the difference between their old, listless dragged-out feeling and new vitality. "That said drug, when caused to be introduced and delivered for introduction into interstate commerce, as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352 (f) (1) in that the labeling of said drug failed to bear adequate directions for use for the purposes and conditions for which it was intended, namely, for the treatment of persons over 35 years old to combat that feeling of growing old; to relieve those suffering from tiredness, weakness, nervousness and run-down condition; to overcome the deficiencies that help drag one down; for premature advancing age; to furnish a whole new world of buoyant energy, vitality and strength by relieving and overcoming the basic causes of their nutritional deficiencies; to help those who feel years older than their age to enjoy life again; to regain vigor and vibrant energy; and to enable thousands of men and women to work harder, and to cause the difference between their listless dragged-out feeling and new vitality; which are the purposes and conditions for which said drug was offered in the newspaper advertisements appearing in the January 22, 1952, issue of the Peoria Journal, which newspaper advertisements were sponsored by and on behalf of said defendants."

vide and Vitamin B₆ has not been established.
The need in Human Nutrition for Calcium Pantothenate, Choline, Inositol, dl-Methionine, Folic Acid and Vitamin B₁₂ has not been established.

"At approximately the same time and in connection with the shipment of the same drug, the defendants also shipped in interstate commerce from Omaha, Nebraska, to Topeka, Kansas, consigned to Jayhawk Drug Company, 1001 Kansas Avenue, Topeka, Kansas, a number of display posters entitled, and bearing the introductory language,

If you are over 35
If you are getting that growing old feeling . . .
A True Geriatric Formula Designed
Especially for Advanced Age Groups To Help
You Enjoy Life Again

Those posters were by the defendants designed to be used for the purpose of interesting prospective customers in the purchase, and stimulating the sale, of the drug thus transported. On August 10, 1951, some of such posters, the exact number being uncertain, were publicly displayed in the Jayhawk Drug Store, 1001 Kansas Avenue, Topeka, Kansas, in such manner that each such poster could be and was used in the disposition and sale of the drug.

"On August 6 and 7, 1951, a full page newspaper advertisement for the drug, 'Lipitrons' appeared in Topeka State Journal and Topeka Daily Capital, respectively, newspapers of general circulation in and around Topeka, Kansas, which advertisements, and each of them, were sponsored and paid for in whole or in part by the defendants. Each such advertisement, in large and attention challenging type, opened with the words,

If you are over 35 years old If you are getting
that "growing old" feeling Science has now found
how to fight that feeling of "growing old"

LIPITRONS

For You if you feel tired and weak and Rundown!
For You to help you Recapture Lost Vitality and
Strength!
For You to combat Nervousness, Lack of Vigor and
Energy!

Much other material in that advertising advanced the contention that the drug, 'Lipitrons' was effective to remedy the so-called feeling of 'growing old' and to intercept the experience of feeling tired, weak and rundown, and to help its takers to recapture lost vitality and strength and to combat nervousness, and lack of vigor and of energy and to enjoy life again. And again, in attractive large letters each advertisement closed with the following advice: 'Start yourself, right now, taking a single Lipitron each day! Mail and phone orders filled same day received. JAYHAWK DRUG.'

"Shortly prior to October 16, 1951, and in any event within three years prior to the date of the filing of the information herein, the defendants within the Omaha Division of this District introduced and caused to be introduced for shipment in interstate commerce from Omaha, Nebraska, to Topeka, Kansas, consigned to Jayhawk Drug Company at Topeka, Kansas, a number of bottles, each containing a drug bearing the label of, and in part identifying the contents as, 'Guardian Lipitrons.' Affixed to and displayed upon each of said bottles was a label containing the same description of contents and directions already quoted in connection with the previous similar shipment. At approximately the same time, and in connection with the shipment last above mentioned, the defendants also shipped in interstate commerce from Omaha, Nebraska, to Topeka, Kansas, consigned to Jayhawk Drug Company, 1001 Kansas Avenue, Topeka, Kansas, a number of display posters entitled and bearing the introductory language quoted, supra, from similar posters already identified. These latter posters were by the defendants designed to be used for the purpose of interesting prospective customers in the purchase, and stimulating the sale, of the drug thus transported. On October 16, 1951, some of such posters, the exact number being uncertain, were

publicly displayed, along with some of the bottles containing the drug, in the Jayhawk Drug Store, 1001 Kansas Avenue, Topeka, Kansas, in such manner that each such poster could be and was used in the disposition and sale of the drug.

"On September 24 and 25, 1951, newspaper advertisements, each an entire page in length and approximately two-thirds page in width, devoted largely, but not entirely, to the advertisement of the drug, 'Lipitrons,' appeared in Topeka State Journal and Topeka Daily Capital, respectively. Both of those advertisements were sponsored by and paid for, in whole or in part, by the defendants. Those advertisements contained all of the material quoted above from the advertisements of August 6 and 7, as well as much other material advancing the contention that the drug, 'Lipitrons' was effective to remedy the so-called 'feeling of growing old and to intercept the experience of feeling tired, weak and rundown, and to help its takers to recapture lost vitality and strength and to combat nervousness and lack of vigor and of energy, and to enjoy life again.' The advertisements of September 24 and 25, 1951, closed with the designation of 'Jayhawk Drug, 1001 Kansas Avenue' which it described as featuring 'every vitamin for every purpose' and as 'largest exclusive vitamin institution in Topeka.'

"On or about January 11, 1952, the defendants shipped in interstate commerce from Omaha, Nebraska, to Peoria, Illinois, consigned to Peoria Health Food Center, 131 North Jefferson Avenue, Peoria, Illinois, a number of bottles, each bearing a label designating its contents as 'Guardian Super Lipitrons.' Affixed to and displayed upon each of said bottles was a label containing the following printed and graphic material:

EACH CAPSULE CONTAINS:

Vitamin B ₁	15 mgm.
Vitamin B ₂	6 mgm.
Vitamin C.....	50 mgm.
Niacinamide.....	30 mgm.
Calcium Panthotenate.....	3 mgm.
Vitamin B ₆	0.5 mgm.
Liver Concentrate.....	30 mgm.
Choline Dihydrogen Citrate.....	20 mgm.
dl-Methionine.....	20 mgm.
Inositol.....	20 mgm.
Iron as Ferrous Gluconate.....	30 mgm.
Folic Acid.....	0.1 mgm.
Vitamin B ₁₂ USP (Crystalline).....	3 mcg.

And the same label also contained the following printed and graphic material:

A DIETARY SUPPLEMENT

DIRECTIONS: Adults—One capsule per day or as directed by the physician. Each capsule supplies the following ration of the minimum adult daily requirements: 1500% of Vitamin B₁, 300% of Vitamin B₂, 167% of Vitamin C, and 33% of Iron. The daily adult requirement for Niacinamide and Vitamin B₆ has not been established. The need in Human Nutrition for Calcium Pantothenate, Choline, Inositol, dl-Methionine, Folic Acid and Vitamin B₁₂ has not been established.

"At or about the same time the defendants also shipped from Omaha, Nebraska, to Peoria, Illinois, and to the said Peoria Health Food Center, as consignee, a number of display posters entitled, and bearing the introductory language:

IF YOU ARE OVER 35
If You Are Getting That
"GROWING OLD" feeling
Advanced Formula
LIPITRONS, A True Geriatric

Formula Designed Especially For
Advanced Age Groups
To Help You
ENJOY LIFE AGAIN

Those posters were by the defendants designed to be used for the purpose of interesting prospective customers in the purchase, and stimulating the sale, of the drug described as 'Guardian Super Lipitrons' thus transported, and along with bottles containing such 'Guardian Super Lipitrons' were publicly displayed by the said Peoria Health Food Center.

"On January 22, 1952, a newspaper advertisement, approximately three-fourths of a page long and five columns wide, appeared in the Peoria Journal, a newspaper of general circulation in and around Peoria, Illinois, which advertisement was sponsored and paid for, in whole or in part, by the defendants. Such advertisement in large and attention challenging type opened with the words:

IF YOU ARE OVER 35 YEARS OLD!
IF YOU FEEL "OLD" BEFORE YOUR TIME!
NOW! Combat that Feeling of "Growing Old"!

Much other material in that advertisement advanced the contention that the drug 'Lipitron' was effective to remedy the so-called feeling of 'growing old' and to intercept the experience of feeling tired, weak and rundown and to help its takers to recapture lost vitality and strength, and to combat nervousness and lack of vigor and energy, and to enjoy life again. The advertisement closed with the identification of 'HEALTH FOOD CENTER, 131 Jefferson Ave., Peoria' as the advertiser.

"The composition of the drugs contained in the several bottles above referred to was exactly the same as to nutrition and quality, with respect to each exhibit, as stated and represented on the printed label on each such exhibit.

"While the several posters above mentioned were prepared by the defendants and by them were designed for use in the promotion and furtherance of the sale of the drugs shipped by the defendants to the several indicated consignees, the posters were not in any instance transported in the same package, carton or wrapper as a shipment of the drugs to which they respectively referred. The posters were, however, shipped at about the same times when the related shipments of drugs were made to the several consignees of the posters.

"Concerning the several newspaper advertisements, it is not proved—nor, indeed, is it charged—that the newspaper mats or plates, or other material for their printing or composition, were, by the defendants, or either of them, shipped at any time in interstate commerce. The defendants are shown merely to have sponsored and, wholly or in part, to have paid for those advertisements which were timed strategically to inspire and stimulate the local retail sales of the drugs which were by the defendants introduced into and transported by interstate commerce.

"Not by stipulation, but upon the oral evidence³ received on the trial, the following further findings are made:

"As a practical matter it is impossible, without immediate and individual clinical examination of a person, to prescribe for his treatment the taking of the so-called vitamin drugs. His need for specific vitamin bearing substances and for appropriate quantities thereof must first be established. And this can not be done by the manufacturer of drugs upon a generalized basis applicable alike to all potential patients through resort to self diagnosis. Attempts in that direction are either without any effect or actually evil through

³ It can hardly be considered that the oral evidence is in dispute. For the plaintiff three scientific expert witnesses testified. One was the president of the American Geri-ontological Society, a physiologist of world-wide celebrity, with many years of experience in teaching and research, of which more than fifty years were spent in the University of Chicago. The second was a Doctor of Philosophy and a Doctor of Medicine, the professor of Biological Chemistry and Nutrition in the College of Medicine of Creighton University, a man of preeminence and distinction in his field. And the third was a practicing physician of Omaha who is also an instructor in internal medicine and geriatrics in the College of Medicine of the University of Nebraska. Their testimony was not repelled by opposing evidence. Each of them was subjected to appropriate cross examination. But the cross examination was ineffective to impair their direct evidence.

the reception of improper substances or of generally meritorious substances in doses unsuitable to the needs of the patients.

"Assuming the presence, in the transported capsules of the drugs, of the elements in the quantities designated on the several bottle labels, the capsules if taken in the quantities suggested on the labels could have no possible retarding or corrective effect upon the aging process or upon the 'feeling of growing old.' Nor would they have any effect in enabling their takers to 'recapture lost vitality' if the loss of vitality were incident to old age. There is actually no available medicinal remedy for the loss of vitality in consequence of old age

"While certain of the ingredients of the tablets, e. g., Choline Dihydrogen Citrate, Inositol, and dl-Methionine, are recognized as lipitrophic agencies, and are helpful in some cases, the tablets here involved contain such small quantities of those ingredients that their lipitrophic effect in any instance would be slight, and, in cases of substantial deficiency, altogether insignificant.

"Despite the representations of the labels, the product involved is not actually a 'high potency lipitron' or a 'super lipitron' and may not accurately or properly be so characterized.

"The charge against the defendants does not involve any impurity or adulteration, and the evidence discloses no such action. The products shipped, in respect of the general nature, quantity and purity of their ingredients were as represented. They are not dangerous or harmful to human health.⁴

"The labeling of the transported products did not bear adequate directions for use for the several purposes and conditions for which it was intended, as such purposes and conditions were enumerated and set out in the several newspaper advertisements whose publication has already been found.

"On September 5, 1952, in the court of this division and district, United States of America filed in Civil Action No. 79-52 a libel of information praying for the forfeiture of a large quantity of drugs, including sundry items designated as Super Lipitrons in the possession of the corporate defendant to this action, upon the ground that such drugs were misbranded while held for sale after shipment in interstate commerce within the meaning of Title 21 U. S. C. A., Section 352 (f) (1) in that the label thereon failed to bear adequate directions for the use for which the drugs was intended. On the same day an order for writ of attachment, monition and publication was made and given by this court in such civil action, directing that, besides the publication of an appropriate citation, a copy of such citation be served on the president of the corporate defendant hereto. Thereafter, on September 17, 1952, the corporate defendant hereto made answer to such libel of information, claiming to be the owner of said drugs, consenting to the entry of a decree of condemnation or forfeiture thereof as misbranded and praying for the redelivery to it of such drugs, pursuant to the terms and provisions of Title 21 U. S. C. A., Section 334 (d). On September 17, 1952, with the written approval of counsel for United States of America and counsel for the corporate defendant hereto, decree of condemnation was entered in said civil proceeding in which, among other things, it was directed that the marshal for this district release said drugs to the custody of the corporate defendant hereto under appropriate bond, to the end that the corporate defendant hereto might within a time limited in said decree bring said drug into compliance with the provisions of the Federal Food, Drug and Cosmetic Act under the supervision of a duly authorized representative of the Federal Security Administrator by destroying any portion of such drugs which might be misbranded and by properly relabeling the remainder of said drugs and otherwise conforming with the requirements of the duly authorized representative of the Administrator. Thereafter, the corporate defendant hereto, under the direction and to the satisfaction of the Federal Security Administrator, relabeled the drugs seized in said civil action which were, thereupon, by the Administrator released to the corporate defendant hereto for disposition, and on March 31, 1953, upon application by the United States of America, an order of this court was duly made and given exonerating the bond and discharging

⁴This finding must not be understood to impair the finding of the inadequacy of the products to cure, correct or improve the conditions for which they are recommended by the defendants. The court recognizes that a measure of danger or harm may result from hope thus inspired and left unsatisfied.

the surety in connection with the bond theretofore given by the corporate defendant in such civil proceeding.

"By Title 21 U. S. C. A., Section 331, it is provided that:

The following acts and the causing thereof are hereby prohibited:

- (a) The introduction or delivery for introduction into interstate commerce of any drug that is misbranded.

"Penalties for the violation of Title 21 U. S. C. A., Section 331 are provided by Title 21 U. S. C. A., Section 333 (a) and (b) as follows:

(a) Any person who violates any of the provisions of section 331 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 331, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

It is noted that presently immaterial exceptions from punishability are made by subsection (c) of the same section.

"The terms 'drug' and 'label' and 'labeling' are defined by Title 21 U. S. C. A., Section 321, which, among other things, declares that:

(g) The term "drug" means (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or function of the body of man or other animals.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article of any of its containers or wrappers, or (2) accompanying such article.

"The definition of misbranding is contained in Title 21 U. S. C. A., Section 352. So far as is pertinent here, it follows:

A drug shall be deemed to be misbranded—

- (a) If its labeling is false or misleading in any particular.
 (f) Unless its labeling bears (1) adequate directions for use;
 (j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.⁵

"By Title 21 U. S. C. A., Section 371 (a) Congress has declared that:

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section,⁶ is vested in the Secretary.

"Within that authority, the Secretary has promulgated the following regulation touching the inadequacy of directions for use of drugs (see Title 21 C. F. R. Section 1.106 (a) (1)):

⁵ It will already be apparent that the court does not consider that within the meaning of subsection 352 (j), the drug transported was "dangerous to health" in any reasonably strict meaning of that phrase. Any such danger would seem to arise, if at all, not from the direct effect of the drug, but from its ineffectiveness (see footnote 4, supra).

⁶ The exceptions are not material in this proceeding.

1.106 Drugs; directions for use (a) Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part, or incorrect specification of:

- (1) Directions for use in all conditions for which such drug is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or in behalf of its manufacturer, packer, or distributor, or in such other conditions, if any there be, for which such drug is commonly and effectively used;
- (2) Quantity of dose (including quantities for persons of different ages and different physical conditions);
- (3) Frequency of administration;
- (4) Duration of administration;
- (5) Time of administration (in relation to time of meals, time of onset of symptoms, or other time factor);
- (6) Route or method of administration.;
- (7) Preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

"The court does not understand the government to contend that any of the several newspaper advertisements should be considered within the definition of 'labeling.' It is not so charged in the information. The contention is that those advertisements, sponsored, and wholly or partly paid for by the defendants, constitute recommendations or suggestions by the defendants themselves of conditions for the use of the drugs, and, therefore, are entitled to be considered in determining whether the directions for their use are inadequate within the definition of Title 21 C. F. R., Section 1.106, supra. The court regards that contention as well taken. Thus limited, it is not necessary to prove, nor is it averred in the information, that any such advertising (or the material thereof or plates or mats therefor) accompanied the drug or any shipment thereof, within the meaning of Title 21 U. S. C. A., Section 321 (m), supra. Indeed, the defendants are not charged with the 'introduction or delivery for introduction into interstate commerce' of any such advertising material or of the equipment for it.

"It is charged, and as the court considers fully proved, that the several display posters 'accompanied' the drugs within the intendment of Title 21 U. S. C. A., Section 321 (m). Upon that premise, and regard being had to its language and actual and intended use, each such poster constituted 'labeling' of the drug. That the posters accompanied the drugs seem to be conclusively settled. *Kordel v. United States* 335 U. S. 345 (affirming *United States v. Kordel* (7 cir) 164 F (2) 913); *United States v. Urbuteit* 335 U. S. 355; *United States v. Kaadt* (7 Cir.) 171 F (2) 600; *Alberty Food Products v. United States* (9 cir) 194 F (2) 463. They were shipped by the defendants to the consignees of shipments of the drugs as a part of the defendants' program for the marketing of their product and, though not in the same packages, or even at the identical time with the drugs themselves, at such times as were calculated to further the sales to ultimate consumers of the drugs. No more is required for 'accompaniment.' Upon this subject the cited opinions, supra, are conclusive. This is particularly true of *Kordel v. United States*, supra, which is given an added significance by a dissenting opinion that serves to emphasize the full consideration which the issue received. In the majority opinion, Mr. Justice Douglas says:

In this case the drugs and the literature had a common origin and a common destination. The literature was used in the sale of the drugs. It explained their uses. Nowhere else was the purchaser advised how to use them. It constituted an essential supplement to the label attached to the package. Thus the products and the literature were interdependent, as the Court of Appeals observed.

It would take an extremely narrow reading of the Act to hold that these drugs were not misbranded. A criminal law is not to be read expansively to include what is not plainly embraced within the language of the statute (*United States v. Resnick*, 299 U. S. 207; *Kraus & Bros. v. United States* 327 U. S. 614, 621-622), since the purpose fairly to apprise men of the boundaries of the prohibited action would then be

defeated. *United States v. Sullivan* 332 U. S. 689, 693; *Winters v. New York* 333 U. S. 507. But there is no canon against using common sense in reading a criminal law, so that strained and technical constructions do not defeat its purpose by creating exceptions from or loopholes in it. See *Roschen v. Ward* 279 U. S. 337, 339.

"Without needless emphasis, it may be observed that the opinion's thought touching a common sense approach to construction may be given effect in appraising the present defendants' argument, fortified by the citation of *Alberty v. United States* (9 cir) 159 F (2) 278, for a more strict construction here of the cited sections of Title 21 U. S. C. A. than would be allowable if the action were one in forfeiture, or a Federal Trade Commission proceeding. Recognizing the abundant literature which supports a construction of criminal statutes more strict than that accorded in civil actions concerning the same subject, a court must not by narrow construction emasculate an otherwise plain criminal statute. Perversion too often and too easily results from an avowed attempt to construe a legislative enactment either strictly or liberally. The consequence is the distortion of the statute to support a foreordained judicial objective. Legislative language is generally most faithfully construed when it is held to mean simply what it says, read with common sense. See also *Dotterweich v. United States* 320 U. S. 277; *United States v. One Device, etc.* (10 cir) 160 F (2) 194; and *United States v. 7 Jugs of Rakos* (D. C. Minn.) 53 F. Supp. 746. And for a direct consideration of *Alberty v. United States*, supra, see *United States v. Kordel* (7 cir) 164 F (2) 913 at p. 917.

"A specific criminal intent, an awareness of wrongdoing is not charged against the defendants, or either of them. Nor is it by the cited statute made an essential element of the offenses described in the information. *United States v. Dotterweich*, supra; *United States v. Kaadt*, supra; *United States v. Greenbaum* (3 cir) 138 F (2) 437. See also, though in a condemnation case, *United States v. 11¼ Dozen Packages, etc.* (D. C. N. Y.) 40 F. Supp. 208.

"The falsity or misleading character of a label or of labeling or of advertising is to be measured by its significance as read by those to whom it appeals. *Aronberg v. Federal Trade Commission* (7 cir) 132 F (2) 165; *D. D. Corporation v. Federal Trade Commission* (7 cir) 125 F (2) 679; *Newton Tea & Spice Co. v. United States* (6 cir) 288 Fed. 475; *Charles of the Ritz Distributors Corp. v. Federal Trade Commission* (2 cir) 143 F (2) 676; *Bockenstette v. Federal Trade Commission* (10 cir) 134 F (2) 369; *Colgrove v. United States* (9 cir) 176 F (2) 614 (cert. den. 338 U. S. 911). Counsel for the several parties extensively discuss in their briefs the intellectual level of the prospective customer by which the appeal of such material is to be measured. It seems from the authorities, supra, to be established that the test is neither the significance of the publicity to observers of notably superior intelligence nor its appeal to the mentally dull or infirm, but rather its attraction to people of ordinary understanding and discrimination. The reaction of the average person is thus made the test. But allowance has also to be made for the susceptibility to the publicity of the groups or types of people at whom it is peculiarly aimed. The present drugs and their supporting publicity would have no appeal, and little meaning, to young persons, athletes, high school or university students, or youthful workers or business or professional people. But it is quite otherwise with men and women beyond middle age, the so-called older folk of the type pictured in the challenged newspaper advertising. As most members of the federal judiciary will at once realize, those oldsters need little more than a vagrant suggestion to lead them to hope in the restorative ministry claimed for the defendants' tablets. Their publicity advances a message they are longing to read or hear, and with pathetic eagerness they receive and embrace it. They must especially be regarded in these circumstances, for it is to them and their faltering faculties, physical and mental, that the message of the labeling is oriented. Thus understood, the court has no difficulty in concluding that the labels and labeling are false and misleading. What, indeed, can be more cruelly false and misleading than the inspiration of hope in one for whom actually there is no hope?

"Upon the facts clearly established the court finds and concludes, in connection with each of the three separate shipments of drugs and posters that the labeling therein effected was false and misleading in the several respects

and particulars set out in the information, and, therefore, constituted a misbranding, first, without reference to the newspaper advertising related to the respective shipments. That conclusion alone warrants the conviction of both defendants upon each of the three counts. For it is sufficient to support conviction on the ground of the shipment of a misbranded drug, that the labeling be 'false or misleading in any particular.' Title 21 U. S. C. A., Section 352 (a), in relation to Title 21 U. S. C. A., Sections 321 (a) and 331 (a). *United States v. One Device*, supra; *United States v. Dr. David Roberts Veterinary Co., Inc.* (7 cir) 104 F (2) 785.

"But the court, secondly, finds and concludes that misbranding of the drugs thus shipped existed in each instance also because of the failure of the labeling to bear 'adequate directions for use,' within the meaning of Title 21 U. S. C. A., Section 352 (b), regard being had to the varied conditions for which the 'drug' was 'prescribed, recommended, or suggested in its labeling' and 'in its advertising sponsored by or in its behalf by its manufacturer, packer or distributor,' i. e. the defendants, within the meaning of Title 21 C. F. R. Section 1.106 (a) (1). In the final phase of this conclusion rooted in 'advertising' the court has in view the newspaper advertising received in evidence. That advertising is not itself an offense against the Act denounced in the present information. But it is the defendants' own 'recommendation and suggestion' respecting the use of the drug, by which in part the adequacy of the labeling's 'direction for use' is to be appraised.

"It may be stated very briefly that the court does not regard the proceedings in Civil Action No. 79-52, supra, as a defense to the charges against the defendants. Their offense, if any, antedated the prosecution of the civil suit, and was complete long before Case No. 79-52 was commenced. And nothing which occurred in the civil action even assumes to affect the defendants' criminal liability for the earlier shipment of drugs comparable in character to those proceeded against in the civil case.

"The court, therefore, finds and adjudges the defendants, and each of them, to be guilty as charged, and convicts the defendants, and each of them, of the charges against them, in each of the three counts of the information.

"Concerning the sentence to be pronounced, it is considered that only the opening portion of Title 21 U. S. C. A., Section 333 (a), has present application. No situation drawn to the court's attention would warrant resort to the more severe provision of subsection (a) or to subsection (b) of the same section. The maximum allowable sentence for each defendant under each count is, therefore, imprisonment for not more than one year (applicable, of course, only to an individual defendant) or a fine of not more than \$1,000.00 or both such imprisonment and fine. Maximum sentences ought rarely to be resorted to unless the circumstances of the offense are aggravated. Whatever the facts may be, no aggravating features of the offenses under prosecution have been established.

"The court has resolved to, and does, sentence the defendant, Vitamin Industries, Inc., to pay a fine of \$150.00 upon each of the three counts of the information (in all \$450.00) and, in addition thereto, the costs of this action, and the defendant Joseph L. Zweiback to pay a fine of \$50.00 upon each of the three counts of the information (in all \$150.00). No sentence to imprisonment is imposed or considered to be warranted."

4585. Anterior pituitary aqueous extract. (F. D. C. No. 37041. S. No. 83-979 L.)

QUANTITY: 36 cartoned vials at Minneapolis, Minn.

SHIPPED: Between 2-25-54 and 4-9-54, from Indianapolis, Ind., by Pitman-Moore Co.

LABEL IN PART: (Vial) "10 cc. Size Parenteral Solution Extract of Anterior Pituitary Aqueous Each cc. contains the water soluble extractive from 18½ grs. of fresh anterior pituitary. Chlorobutanol (chloral deriv.) 0.5% (Preserv.). Caution: To be dispensed only by or on the prescription of a veterinarian. Warning: Contains no known therapeutically active principle derived from anterior pituitary for which recognized methods of assay exist."