DIVISION OF HEALTH:
DRUGS AND DRUGGISTS: Any person who sells, delivers, or offers for sale any new drug that has not been tested and approved as safe for use by either the Federal Food and Drug Administration or the Division of Health of Missouri shall be guilty of a misdemeanor.

February 9, 1950

Division of Health
Bureau of Public Health Engineering
Jefferson City, Missouri

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Dear Mr. McCutchen:

I.

In answer to the request by your Bureau for an official opinion from this office upon the following facts as stated in your letter:

> "We find that since your first opinion concerning the lectures of Lelord Kordel, that Mr. Kordel has left the state.
>
> "We have under embargo at the New Dawn Health Food Store Warehouse in St. Louis, Missouri, drugs labeled as 'Sodeum,' 'Vero B. Flex,' 'Minerals Daily,' '1-Combs' and 'Korleen.' Because of the claims made by Mr. Kordel for these drugs, we believe they are misbranded under Section 9870, paragraph (f) (1) see regulation (a). Since the New Dawn Health Food Store has sponsored these lectures we believe they have violated Section 9858, paragraph (c), also Section 9874. See also Section 9857, paragraph (k).
>
> "We are attaching herewith a copy of the recorded lectures of Mr. Kordel in which he stated that these drugs may be obtained from the New Dawn Health Food Store.
>
> "We request an official opinion if such oral claims for these drugs are misbranding or if the New Dawn Health Food Store is violating any other Section of the Food and Drug Laws, since they have sponsored these lectures by Mr. Kordel.

> "Further, if the New Dawn Health Food Store has violated the Food and Drug Laws, is such a violation a misdemeanor?"

we have considered the copies of the recorded lectures of Mr. Lelord Kordel and the statutory provisions relating thereto.

II.

Section 9857, Reenacted Laws 1943, page 559, provides at subsection (h) as follows:

> "(h) The term 'label' means a display of written, printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act, that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

At subsection (j) it is stated:

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

The Federal Food, Drug and Cosmetic Act as enacted in 1938, 21 U.S.C.A., Section 321, has similar provisions. The courts have construed such provisions in several cases, but we cannot find any cases holding that labeling would include verbal statements or representations.

The lectures of Mr. Kordel were, without question, advertising, but we believe that the term labeling as defined in our said section 9857, supra, means labels or other written, printed or graphic material and not verbal statements. But if the labeling was misleading then under subsection (k) of said Section 9857, supra, then representations made or suggested by statement, word, design, device, sound, or in any combination thereof may be taken into account to determine the extent to which the labeling fails to label the material facts. We do not know whether or not the

labeling on the drugs mentioned in your letter are misleading or not.

Section 9858, Reenacted Laws of 1943, page 559, prohibits the dissemination of any false advertisement and also prohibits the sale of any article in violation of Section 9871.

Mr. Kordel held himself out as the representative in said lectures of the New Dawn Food Store and stated that they were sponsoring him. If it can be proved he was their agent then they would be liable for any false advertisement or advertising that he did in said lectures.

Section 9874, Reenacted Laws 1943, page 559, defines false advertisement as follows:

> "An advertisement of a food, drug, device, or cosmetic shall be deemed to be false if it is false or misleading in any material respect."

In the case of U.S. v. Lelord Kordel, 164 Fed. Rep.(2d) 913, in which he was convicted of violations of the Federal Food, Drug and Cosmetic Act, the court said that there can be no serious question about the misrepresentations contained in the literature that he put out with his drugs. The names of the drugs are given in the footnote of said case and included among others, "Fero-B-Plex," "Bolas," "Ribotabs," "Ormotabs." The pamphlet that the court considered in this case was used primarily for promoting the sale of the various products by explaining the need for each. His lectures do the same thing.

We also believe that they would be liable under Section 9871, Reenacted Laws 1943, page 559, if they were selling and offering for sale new drugs that had not been filed with the Division of Health of the State of Missouri or with the Federal Food and Drug Administration as required by said section. Section 9871, supra, provides as follows:

> "(a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has become effective under Section 505 of the Federal Act, or (2) when not subject to the Federal Act unless such drug has been tested and has not been found to be unsafe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the Board an application setting forth (a) full reports

of investigations which have been made to show whether or not such drug is safe for use; (b) a full list of the articles used as components of such drug; (c) a full statement of the composition of such drug; (d) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug; (e) such samples of such drug and of the articles used as components thereof as the Board may require; and (f) specimens of the labeling proposed to be used for such drug.

"(b) An application provided for in subsection (a) (2) shall become effective on the 60th day after the filing thereof, except that if the Board finds after due notice to the applicant and giving him an opportunity for a hearing, that the drug is not safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, the Board shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

"(c) This section shall not apply--

"(1) to a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety in drugs provided the drug is plainly labeled 'For investigational use only'; or

"(2) to a drug sold in this State at any time prior to the enactment of this Act or introduced into interstate commerce at any time prior to the enactment of the Federal Act; or

"(3) to any drug which is licensed under the virus, serum, and toxin Act of July 1, 1902 (U.S.C. 1934 ed. title 42. Chap. 4).

"(d) An order refusing to permit an application under this section to become effective may be revoked by the State Board of Health."

Mr. Kordel stressed in his lectures that the drugs that they had for sale at the New Dawn Food Store were new drugs made in Missouri and for sale in Missouri. Your department has informed

me that said drugs have not been filed with your department as required by this section and that said drugs do not come within the exceptions set forth in said Section 9871, supra.

Section 9862, Reenacted Laws 1943, page 559, reads as follows:

> "It shall be the duty of the Prosecuting Attorney in any county or city in the state, when called upon by the State Board of Health, or any of its assistants, to render any legal assistance in its power to execute the laws and to prosecute cases rising under the provisions of this article. Before any violation of this Act is reported to any such attorney for the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views before the State Board of Health of its designated agent, either orally or in writing, in person, or by attorney, with regard to such contemplated proceeding. The court at any time after seizure up to a reasonable time before trial, shall, by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized, and as regards fresh fruit or vegetables, a true copy of the analysis on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyses were obtained."

The statute requires you to give the defendants notice in writing of any contemplated criminal action and to give them an opportunity to present their views before the Division of Health or its designated agent.

CONCLUSION

Any person who shall sell, deliver, offer for sale, hold for sale or give away, any new drug that has not been approved by the Food and Drug Administration of the United States Government in accordance with Section 505 of the Federal Food, Drug and Cosmetic Act or if said drug is not subject to the Federal Act, and has not been tested and approved as safe for use by the Division of Health of the State of Missouri, shall be guilty of a misdemeanor and subject to criminal prosecution, unless the said new drug comes within the specifications stated in Section 9871, Reenacted Laws, 1943, page 559.

APPROVED:

Respectfully submitted,

J. E. TAYLOR
Attorney General

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