

FOOD AND DRUG: Sale, etc. of any drug not branded with adequate directions for the use thereof is misbranding under and a violation of Food and Drug Act.

November 28, 1949



Mr. C. F. Adams, M.D.,  
Acting Director,  
Division of Health,  
State Office Building,  
Jefferson City, Missouri

Dear Dr. Adams:

Your request for an official opinion from this Department, dated November 1, 1949, together with letter addressed to Mr. J. L. Rowland, Director, Bureau of Foods and Drugs, State Board of Health, Jefferson City, Missouri, dated October 18, 1949, signed by W. A. Queen, Chief, Division of State Cooperation, with other information attached, has been assigned to the writer for reply. Your opinion request reads:

"We would like to have an official opinion from your department concerning the attached case in regard to lectures by Mr. Lelord Kordel, operating for New Dawn Health Food Store, St. Louis, Missouri.

"We would like to know if inadequate directions for use of these products may be considered misbranding under our State Food and Drug Laws, and if it would be advisable to prosecute the party or parties responsible in this case.

"Our local inspector has obtained samples of all these products and our laboratory is at the present time engaged in analytical work to determine if the products in question contain the chemicals and vitamins which have been indicated on the label."

In answering your letter, I assume that Mr. Lelord Kordel at the times and place mentioned in the letter to Mr. Rowland was delivering a lecture or lectures seeking to promote or accelerate sales of the products mentioned in the letter last referred to; and I assume that at the times and place of the lecture or lectures delivered by Mr. Kordel, he did not offer to sell direct to his

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listeners, container or containers holding such product; and I assume that the products mentioned were in containers and being offered for sale, delivery, or held for sale by the concern referred to as, "New Dawn Health Food Store", St. Louis, Missouri, and that the container or containers did not bear a label stating adequate directions for use of the product by consumers thereof; and, I am assuming also that the containers were not accompanied, in a package or otherwise, by written or printed instructions giving adequate directions for use of the product; I am also assuming the products mentioned in the letter to Mr. Rowland contain drugs within the meaning of Section 9857, (d) Laws of Missouri, 1943, p. 561.

1. Section 9858, Laws of Missouri, 1943, p. 563, among other things, provides as follows:

"The following acts and the causing thereof within the State of Missouri are hereby prohibited:

"(a) The \* \* \* sale, or delivery, holding or offering for sale of any \* \* \* drug, device, \* \* \* that is \* \* \* misbranded.

"(e) The dissemination of any false advertisement."

The terms "label", "immediate container", "labeling" and "misbranded", as set out in Laws of Missouri, 1943, p. 562 are 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.

"(i) The term 'immediate container' does not include package liners.

"(j) 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.

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"(k) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."

Section 9870, Laws of Missouri, 1943, p. 572, in part, provides:

"A drug or device shall be deemed to be misbranded -

"(f) Unless its labeling bears (1) adequate directions for use; \* \* \* Provided, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Board shall promulgate regulations exempting such drug or device from such requirements."

I also note that you state Mr. Lelord Kordel was "operating for New Dawn Health Food Store."

2. The regulations issued under the Federal Act quoted in the letter to Mr. Rowland are not helpful, except as they show that the regulation of your Department set out in the same letter is not in conflict with such federal regulations as required by Section 9864, Laws of Missouri, 1943, p. 567; however, I may point out that the only specific direction in the regulation issued by your Department is:

"Directions for use shall include quantity of dose."

The remainder of the quoted regulation is not specific in command and depends for its enforcement on the condition or fact

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that:

"Where it is deemed to be in the interest of the public health for the protection of the consumer."

And consequently, would be of little value in enforcing the State Drug Act. The form of regulations issued under the Federal Act above referred to and as set out in the margin of the opinion in *Colgrove, et al. v. United States* 176, F 2d, 614, hereafter referred to, would appear to be applicable in enforcement of the State Drug Act, if and when properly promulgated.

3.

(a) If violated, we think that a prosecution in our state courts can be successfully maintained in the labeling on articles such as those mentioned or referred to in your letter do not bear adequate directions for use and one of the required directions under your regulation is the quantity of dose of the product to be used by the consumer. Undoubtedly, acts of omission, as well as commission, fall within the ban of the State Drug Act.

Section 9857, (b) Laws of Missouri, 1943, p. 561 in referring to the State Food and Drug Act provides:

"The term 'person' includes individual, partnership, corporation, and association."

If Kordel, at the time he delivered the lecture or lectures had sold, offered for sale, delivered, or held for sale to and for his listeners, any of the mislabeled products referred to in your letter, then he would be guilty of a violation of the Act as it has been heretofore defined or set out, but since it does not appear from your letter that he did any of the things just mentioned, then we see no basis for prosecution against him individually. See cases of *Migratory Bird Treaty Act*, 281 F. 546, 548; *Crawford v. Newark Star Pub. Co.* 183 A. 73 (N.J.); *Hardwick v. Reardon* 6, Ark. 77.

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(b) We cannot gather from your letter whether the New Dawn Health Food Store is owned individually, as a partnership, voluntary association of persons, or a corporation but, whatever that fact may be, if those responsible for the operation of the concern have sold, or have or are offering for sale, or keeping for sale or delivery the products mentioned in your letter, without the same being labeled with adequate directions for its use, including the amount of dosage thereof, then such persons would be liable to prosecution under the State Food and Drug Act and subject to the penalties as provided in Section 9860, Laws of Missouri, 1943, p. 564, upon conditions hereafter set out.

I do not find any reported case in this state construing the State Drug Act in respect to the matters with which we are concerned but a similar problem was before the United States Circuit Court of Appeals in Colgrove et al. v. United States 176, F 2d, 614. The case being an appeal from a conviction for criminal contempt growing out of the violation of an injunction judgment issued by a District Court. The proceeding being had under 21 U. S. C. A. Sec. 332 (a), a provision of the Federal Food, Drug and Cosmetic Act comparable to our State Act. We quote sufficient from the opinion, a copy of which is attached to your letter, so that you may gather its significance as applied to the Act, with the enforcement of which your Department is concerned:

"In 1945 appellants changed the labeling of the Colusa Oil preparations so that the labels failed to mention any maladies for which the drugs were recommended. However, they then proclaimed the worth of the products in the treatment of specified ailments extensively in newspaper advertisements. Early in 1947 the United States sought an injunction in the court below restraining the shipment of the products in interstate commerce without a label containing adequate directions for their use in the treatment of all conditions for which they were prescribed, recommended and suggested in the advertising material. The action was predicated on 21 U. S. C.A. Sec. 352 (f) (1), which provides that a drug or device shall be deemed to be misbranded unless its labeling bears adequate directions for use. A preliminary injunction was granted, D.C. 83 F. Supp. 880, after which the court

issued a permanent injunction with appellants' consent. Appellants then devised a label on which it was stated that the products were intended for use in the treatment of four skin diseases, namely psoriasis, eczema, athlete's foot, and leg ulcers. Specific directions as to the method of use for these affections were incorporated in the label. \* \* \*

"Thereupon the government filed a contempt information containing nine counts, predicated on allegations of nine interstate shipments. The charge in each count is that appellants disregarded the injunctive orders in that the advertising material disseminated by them prescribed, recommended and suggested the use of the oil in the treatment of certain diseases in addition to the four mentioned on the label, and that adequate directions for using the remedy for those diseases were not printed on the label. The information is based on 21 U.S. C. A. Sec. 332 (b). A jury and special findings were waived and upon trial to the court appellants were adjudged guilty on eight counts.

" \* \* \* The Act prohibits the introduction into interstate commerce of any misbranded drug. 21 U. S. C. A. Sec. 331 (a). A drug is deemed misbranded if its labeling bears inadequate directions for use, 21 U. S. C. A. Sec. 352 (f) (1); and as appears in footnote 3 above the authoritative regulations declare directions inadequate if there is an omission of directions for use in all conditions for which the drug is prescribed, recommended or suggested in advertising matter sponsored by the manufacturer or distributor. The court's statutory authority for the issuance of the injunctions and for the trial of violations thereof is ample and has already been indicated.

"Little comment need be made on this advertising; it speaks for itself. Plainly the sponsor intended to be understood as adopting as his own the quoted statements of the doctors and professional dispensers of the preparation. That these would be taken by the lay reader as unqualifiedly prescribing the use of Colusa oil in the treatment of acne and poison ivy, or oak, admits of no fair doubt.

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The term 'prescribed' is given the following definition by Webster: 'Med. To direct, designate, or order the use of, as a remedy.' The word 'designate,' in turn, is defined as 'to mark out and make known; to point out; to indicate.' Neither logic nor fairness requires a narrower definition of the term when employed in flamboyant advertising like the present. The word 'prescribe' of course includes recommending and suggesting.

"Other points urged are unworthy of specific attention.

"Affirmed."

(c) You, of course, are familiar with the provisions of Section 9861 of above laws entitling you to proceed as by condemnation in certain justified circumstances.

Section 9862, Laws of Missouri, 1943, p. 567, makes it the duty of the prosecuting attorney in any county or city in this state when called upon by your Department to render legal assistance in the execution of the State Food and Drug Act and to prosecute the cases arising under the provisions of that law. However, before any violation of the act is reported to the prosecuting attorney for the institution of a criminal proceeding, the person against whom such proceeding is contemplated, should be given appropriate notice and an opportunity to present his views before your Department or its designated agency, either orally or in writing, in person or by attorney, with regard to such contemplated proceeding. It follows, therefore, that any criminal prosecution that may be instituted on the facts stated by you will be done by the prosecuting attorney on the county or city where the crime occurred and before such crime is reported to such prosecuting attorney for the institution of a criminal proceeding, the notice to the proposed defendant or defendants must be given as provided in Section 9862. We do not conclude from a reading of a first portion of Section 9862 that it relates solely to a proceeding in condemnation under Section 9861 penalties provided for in Section 9860 above referred to.

4. For whatever purpose it may serve, we call your attention to that case of United States v. Kordel reported in 164 F. 2d.

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p. 913, wherein a judgment of conviction against the defendant, Lelord Kordel, for violations of the Federal Food, Drug and Cosmetic Act was affirmed. The conviction being obtained in the United States District Court for the Northern District of Illinois Eastern Division. The charge against the defendant, specifically, was for the shipping of drugs and literature alleged to constitute misbranding under the latter Act.

We quote from the opinion in the latter case as follows, at p. 914:

"Appellant is a self-styled authority on nutrition and vitamins. He testified that he had written many papers on the subject of vitamins, herbs, minerals and nutritional diet subjects in general, securing the material for preparation of his papers from books. Operating under various trade names, he had been producing and marketing his own products since January 1941, largely through 'health food' stores. The products appear to be, for the most part, compounded of various vitamins, minerals and herbs. \* \* \*"

And p. 916:

"With respect to the misrepresentations contained in the accompanying literature we think there can be no serious question. The two booklets, 'Nutrition Guide,' and 'What you can do about relieving the agonies of Arthritis,' were written by appellant who, in the latter, is described as 'America's leading vitamin and diet expert.' 'Health Today, Spring 1945,' is edited by the same 'famous nutrition and vitamin authority.' While all purport to be scientific publications of general interest apart from the articles produced and marketed by appellant, written by an expert in the field, in fact, all are replete with references to the Kordel products and their uses to prevent, ameliorate or cure a vast and diverse variety of ailments, and each conveniently closes with a price list of the various Kordel products recommended for use therein. All are concerned primarily with promoting the sale of the various products by explaining the need



for each, along with extravagant claims as to the usefulness of each. A study of the three pamphlets reveals that the products therein described are recommended for relieving stomach agonies, general weakness, anemia, premature old age, high blood pressure, liver troubles, failing eyesight, sore feet; maintaining blood energy, muscular activity, sound teeth and gums, healthy skin, hair and eyes, normal functioning of the pituitary and thyroid glands, stomach, intestines, colon, liver and kidneys; and preventing arthritis and stiff joints, excess weight, catarrh, nervous breakdown, sterility, and paralysis."

This Department does not know and has no opinion as to whether or not the defendant in the case quoted from is the same person as is mentioned in your letter.

5. In connection with what is said in the foregoing Paragraphs 1, 2, and 3 the word "adequate" as used in Section 9870 (f) (1) is defined generally as meaning "sufficient", "enough", "as much as may be necessary", see,

Britain v. Industrial Commission 115 N.E. 110  
Guim v. R. R. Co. 101 N. W. 94  
State v. Builling 105 Mo. 204

And in the sense in which "directions" is used in the latter paragraph subdivisions, the word is generally defined by Webster as the act of directing; guidance; authoritative instruction; information as to method.

6. You inquire of this Department if it would be advisable to prosecute the party or parties responsible in this case - - That is the case you submit:

You understand the problems confronting you in the enforcement of the State Food, Drug and Cosmetic Act and the importance of the omissions as to directions claimed to exist in this case and you are perhaps advised as to the character of the business and persons involved, so that as to whether or not a prosecution should be instituted is a matter that must be determined by your Department, keeping in mind the exceptions set out in Section 9860 above quoted, the admonition contained

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in Section 9863, Laws of Missouri, 1943, p. 567 and also that under the provisions of Section 9862 above referred to, it is your duty to submit to the proper Prosecuting Attorney, the facts in each case where a prosecution is desired or proposed by your Department.

#### CONCLUSION

Upon the facts stated in your letter and the latter addressed to Mr. Rowland, together with the facts assumed as stated in this opinion, it is the opinion of this Department:

(a) That Lelord Kordel in delivering the lecture or lectures referred to did not sell, deliver for sale, hold for sale or offer for sale any article in violation of Section 9867 or 9870.

(b) It is further the opinion of this Department that if the New Dawn Health Food Store sold, delivered for sale, hold or held for sale or are offering for sale the article referred to containing a drug and if such article did not bear or have on the labeling thereof adequate directions for the use of such article, as the words "adequate" and "directions" are above defined, or if such labeling did not contain specific directions for the use of such article in the treatment of all conditions, ills and diseases for which such article was or is prescribed, recommended or suggested, then such omission on the part of the New Dawn Health Food Store would constitute a misbranding by it of such article in violation of the State Food, Drug and Cosmetic Act, if it is a corporation, and the individual or individuals taking part in such illegal acts on behalf of the corporation would also be subject to prosecution therefor, or, if the New Dawn Health Food Store is owned individually or by a partnership or other association of persons, then the person or persons acting for said New Dawn Health Food Store and committing such illegal acts would likewise be criminally liable therefor.

Respectfully submitted,

APPROVED:

GILBERT LAMB,  
Assistant Attorney-General

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J. E. TAYLOR  
Attorney General