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Dear Doctor:

Supplementing the letter I sent you recently regarding the Food and Drug Administration, I wish to add some new information. I have been informed that some of the administration's inspectors have been misquoting the law in order to obtain ampoules that are sent to the physician for treatment of patients and taking advantage of the physician's lack of knowledge of the law.

The second provision of Section 503 of the Food and Drug Act reads as follows:

"(Sec. 503) (b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), shall if—

(1) such physician, dentist or veterinarian is licensed by law to administer such drug, and

(2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian, be exempt from the requirements of Section 502 (b) and (e), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of Section 502 (d)."

"The purpose Congress had in mind in enacting Section 503 of the Act of 1938 is set forth in House Report 2139, 75th Congress, 3rd Session, to accompany Draft S 5. There it is stated that:

'This section also provides for an exemption for drugs dispensed on bona fide prescriptions. Such drugs are relieved from the requirement that the label bear the name and address of the manufacturer, the quantity of the

contents, the common name of the drug, and the name of each of its active ingredients, and if the prescription is non-refillable a warning against habit formation. Such labeling is unnecessary for prescription drugs and, in certain cases, may have an adverse effect on the welfare of the patient.' "

On this subject the Food and Drug Administration ruled on February 21, 1940:

"Correspondent's letter transmitted an order from a physician and a formula for a batch of tablets the physician has been using and which he wishes the correspondent's firm to refill for his use. It is the correspondent's opinion that he may fill and deliver this prescription for the doctor without in any way violating the act, as it would be exempt in accordance with Section 503 (b) (1) and (2).

"A written prescription such as is contemplated in Section 503 (b) of the Act is given by the physician to his patient with appropriate directions for his own personal consumption after it is filled by the druggist. The formula (the one referred to above) is in fact a manufacturing order for goods to be delivered to the physician for ultimate dispensing and not directly to the patient who is to consume it. It is not, therefore, subject to Section 503 (b) (1) and (2) in the opinion of this Administration."

These quotations are taken from "The Law of Foods, Drugs and Cosmetics," by Toulmin, just published. You can readily see from reading the foregoing that we are entirely within the law and that the Food and Drug Department, themselves, agree that they have no right to interfere with our transactions.

Sincerely yours,

Wm F Koch

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