



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
g1675d

WARNING LETTER

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

August 27, 2001

01-PHI-20

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Marvin L. Goldberg, President
Equirace Health and Speed Products
82 Lobell Drive
Washington, PA 15301

Dear Mr. Goldberg:

The agency has completed its review of an inspection conducted December 5, 2000 at Equirace Health and Speed Products (Equirace) by Philadelphia District Investigator Gladys B. Casper. We have also received and reviewed information forwarded to us in July 2001 by the New Mexico Livestock Board regarding your firm's recent promotional activities in that state. Our review finds that your firm is distributing prescription veterinary and human drugs to lay persons without a lawful order from a licensed veterinarian who has a valid veterinarian-client-patient relationship with your customers.

Your prescription veterinary and human drug distribution business violates several sections of the Federal Food, Drug, and Cosmetic Act (the Act). For example, prescription veterinary drugs distributed by your firm are misbranded within the meaning of Section 503(f)(1)(C) of the Act in that they are not dispensed by or upon the lawful written or oral order of a licensed veterinarian in the course of that veterinarian's professional practice. We are aware that you interpret certain state statutes as permitting animal owners to act as "legally entitled attending veterinarians" on their own animals. We note that you have already received a letter from Donald M. Carman, DVM, President of the Maryland Board of Veterinary Medical Examiners, regarding your erroneous interpretation of that particular statute. As a federal agency, however, we can only address the applicable federal statute which, in this case, is the Federal Food, Drug, and Cosmetic Act.

Since your firm receives and distributes prescription drugs in interstate commerce, your business falls under the jurisdiction of the federal government, namely, the Food and Drug Administration (FDA). The FDA is charged with enforcing the provisions of the Federal Food, Drug, and Cosmetic Act. For purposes of the Act, a veterinarian means a person licensed by a State or Territory to practice veterinary medicine (see definition at *Title 21 Code of Federal Regulations* (21 CFR) § 530.3(h)). Unless your customer is a licensed veterinarian, it is unlawful to sell that customer a prescription drug unless such sale is by or on the order of a licensed veterinarian who has a valid veterinarian-client-patient relationship with that customer. A valid veterinarian-

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client-patient relationship is defined at 21 CFR § 530.3(i) and includes the following three elements:

- (1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;
- (2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
- (3) The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

The inspection revealed that, while your partner at Equirace, Franklin Pellegrini, DVM, is a licensed veterinarian, he does not have a valid veterinarian-client-patient relationship with any of Equirace's customers. Further, the inspection found that Dr. Pellegrini's role at Equirace is not to dispense medication in his capacity as a licensed veterinarian but to act as a consultant should a customer have questions about the drugs he or she is purchasing.

In addition, certain prescription veterinary and human drugs offered for sale by Equirace are adulterated within the meaning of Section 501(a)(5) of the Act in that they are new animal drugs that are unsafe within the meaning of Section 512(a)(1)(A) because there are no approved applications filed pursuant to Section 512(b) for their use in horses. Specifically, the following drugs are not approved for use in horses: methocarbamol tablets; Bactrim (sulfamethoxazole/trimethoprim) tablets; isoxsuprine tablets; Baytril (enrofloxacin) injection; and Naquasone (dexamethasone/trichlormethiazide) bolus. Likewise, these drugs are misbranded within the meaning of Section 502(f)(1) of the Act in that their labeling does not contain adequate directions for use of these drugs in horses.

As you may know, the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) permits veterinarians to prescribe certain approved veterinary and human drugs for extralabel uses under certain conditions. However, AMDUCA requires that such extralabel use be made by or on the order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and be in compliance with applicable regulations. These conditions are specified at Sections 512(a)(4)(A) and 512(a)(4)(B) of the Act for approved new animal drugs and Sections 512(a)(5)(A) and 512(a)(5)(B) for approved new human drugs. The regulations are codified at 21 CFR § 530. Equirace customers are not licensed veterinarians as defined by 21 CFR § 530.3(h), and Dr. Pellegrini, a licensed veterinarian, admits that he does not have a valid

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veterinarian-client-patient relationship with Equirace customers. Without a lawful written or oral order from a licensed veterinarian, given within the context of a valid veterinarian-client-patient relationship, none of the provisions identified in 21 CFR § 530 that permit extralabel use of such drugs apply in this case.

We are aware that both you and Dr. Pellegrini had contacted FDA's Philadelphia District Office for information regarding the FDA laws and regulations that apply to your business and that the Compliance Officer responding to your inquiries informed you both of the requirements of Section 503(f) of the Act. You and Dr. Pellegrini were advised that your proposed business would violate Section 503(f) of the Act unless Dr. Pellegrini established a valid veterinarian-client-patient relationship with Equirace customers and/or Equirace dispensed its drugs only by or on the order of a licensed veterinarian who has a valid veterinarian-client-patient relationship with the Equirace customer. Despite this advice, you and Dr. Pellegrini began distributing prescription veterinary and human drugs in interstate commerce to lay persons. Even more troubling is that you have also misrepresented information given to you by FDA in your letter to Dr. Carman of the Maryland Board of Veterinary Medical Examiners and in your August 3, 2000 Open Letter and Statement from Equirace. Specifically, you state in your letter to Dr. Carman that Equirace has "filed a brief with the FDA and has engaged in extensive conversation with Ms. Karyn Campbell." As you know, Ms. Campbell is a Compliance Officer in FDA's Philadelphia District Office. The agency is not aware of any "brief" filed by or on behalf of Equirace; in fact, the only written request for information about Equirace's operations on hand at the agency is a July 10, 2000 letter from Dr. Pellegrini requesting a written ruling from FDA regarding the legality of this business. This letter was sent via facsimile to the Philadelphia District Office which, in turn, referred it to FDA's Center for Veterinary Medicine (CVM) for response. The Philadelphia District Office subsequently advised Dr. Pellegrini via letter dated July 11, 2000 that it had forwarded his request to CVM and had *requested* that office to respond to Dr. Pellegrini in writing. A Compliance Officer from CVM then telephoned Dr. Pellegrini and left a message for him, but Dr. Pellegrini did not return the telephone call.

In your August 3, 2000 Open Letter and Statement from Equirace, you write that "Ms. Campbell told us that FDA would have no problem with the stated business model and would require no federal licensing of Equirace because the right to dispense of a veterinarian is explicitly exempt from federal regulation and that dispensing on a veterinarian to veterinarian basis is not clearly a prescriptive function such that Equirace was acting as a pharmacy." On page 5 of the same letter, you write that you contacted Ms. Campbell after receiving FDA's "intent to issue written opinion" and that Ms. Campbell "reiterated" that she does not believe that "FDA will require licensing from [Equirace] nor will [FDA] claim jurisdiction as to the stated activities." These statements are patently false. Ms. Campbell informed both you and Dr. Pellegrini that your business, as proposed, would violate Section 503(f)(1) of the Act, and Ms. Campbell provided Dr. Pellegrini with a copy of Section 503(f)(1) of the Act. Ms. Campbell also advised Dr. Pellegrini that he may need to receive a license for the business and provided him with a copy of

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the PA Wholesale Prescription Drug Distributors License Act. You should be aware that FDA has the option to issue press to rectify third party statements made about the agency that the agency has found false or misleading.

The above is not intended to be an all-inclusive list of deficiencies at your firm. As top management, it is your responsibility to assure that all of your company's operations are in compliance with the Act and its applicable regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please advise this office in writing within fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct these violations, including an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed. Your reply should be addressed to Karyn M. Campbell, Compliance Officer, Food and Drug Administration, 900 US Customhouse, 2nd & Chestnut Streets, Philadelphia, PA 19106. A copy of your reply should also be sent to Sue Ann Williams, Compliance Officer, Office of Surveillance and Compliance (HFV-200), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District Office



Daniel McChesney, DVM
Acting Director
Office of Surveillance and Compliance
Center for Veterinary Medicine

cc: Franklin Pellegrini, DVM, Vice President and Treasurer
Equirace Health and Speed Products
29 East Pitt #5
Canonsburg, PA 15317