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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

December 2, 2003

WARNING LETTER NYK 2004-02

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Attica Veterinary Associates, P.C.
116 Prospect Street
Attica, NY 14011

Dear Doctors:

An investigation of an illegal tissue residue performed by U.S. Food and Drug Administration Investigators Linda M. Sacco and Michael W. Burd included visits to Attica Veterinary Associates P.C. on February 3 and 6, 2003, and visits to [REDACTED] on December 17, 2002-February 19, 2003, and June 16-26, 2003. The investigation revealed that your practice held for sale veterinary prescription drugs intended for extralabel use without a written or other order of a licensed veterinarian and without benefit of a valid veterinarian-client-patient relationship. Because your practice did not require a prescription and a valid veterinarian-client-patient relationship, you caused these veterinary prescription drugs to be adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, you caused these drugs to be misbranded within the meaning of Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act (the Act).

The investigation revealed that on August 31, 2002, [REDACTED] purchased several prescription veterinary drug products from a [REDACTED] route truck operated by a layperson working for your veterinary practice. Products purchased on that occasion include 12 bottles [REDACTED] 10 units of [REDACTED] and a bottle of [REDACTED]. On or about June 12, 2003, [REDACTED] purchased more of the prescription drug [REDACTED] from a layperson on your [REDACTED] route truck.

The [REDACTED] and [REDACTED] were purchased for extralabel use in the treatment of lactating dairy cows. The label applied to these products by your veterinary practice specifies a four (4) day milk withholding period for these drugs. However, neither of these drugs is approved for use in the treatment of lactating dairy cows. Thus, your practice dispensed these drugs for extralabel use.

Extralabel use of approved animal drugs is permitted under Section 512(a)(4) of the Act provided that such use or intended use is 1) by or on the lawful order of a licensed veterinarian within the context of a veterinarian-client-patient-relationship and 2) in compliance with extralabel use regulations, found in Title 21 of the Code of Federal Regulations (CFR) Part 530. The [REDACTED] and [REDACTED] were dispensed by your veterinary practice for extralabel use without benefit of a lawful prescription and outside the bounds of a valid veterinarian-client-patient relationship. The drugs are therefore unsafe under Section 512(a) of the Act and thus adulterated under Section 501(a)(5) of the Act.

At the time the purchases by [REDACTED] were made, a veterinarian from your practice had not visited the farm since February 12, 2002. Again, under Section 512(a)(4)(A)(i) of the Act, a condition for extralabel use of an approved new animal drug is that such use or intended use is by or on the lawful order of a licensed veterinarian *within the context of a veterinarian/client/patient relationship*. A valid veterinarian/client/patient relationship, as defined in 21 CFR § 530.3(i), exists when:

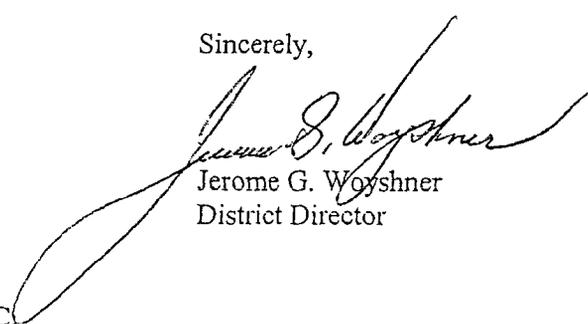
(1) a veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian; and when (2) there 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 when (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 an examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

The prescription drugs dispensed to [REDACTED] are also misbranded because they did not bear adequate directions for use as required by Section 502(f)(1) of the Act, and they do not fall into an exception to that requirement. FDA has defined "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 CFR § 201.5. Under Section 503(f)(1)(A) of the Act, prescription drugs may be used safely only under the supervision of a veterinarian. Directions under which a layperson can safely use prescription animal drugs cannot be written because such drugs can only be used safely under the supervision of, a licensed veterinarian. Thus, adequate directions for lay use cannot be written for the prescription animal drugs dispensed by you. Moreover, you are not exempt from this requirement under Section 503(f)(2)(A) or Section 512(a)(4)(A) of the Act because you dispensed prescription animal drugs without a prescription.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure or injunction.

Please notify this office in writing, within 15 days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address.

Sincerely,



Jerome G. Woyshner
District Director

cc: Charles Baker, Driver
Attica Veterinary Associates, P.C.
116 Prospect Street
Attica, NY 14011