



Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905
Telephone: (913) 752-2100

February 21, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2002-02

Mr. Doug Robertson, Owner
Equine Serum Products, Inc.
392 NE 40th Lane
Lamar, MO 64759

Dear Mr. Robertson:

An investigation regarding your product, "Cycle Pro Pregnant Mare Serum", revealed that you are offering for sale and distributing this product. Based on our investigation this product is a new animal drug that is being marketed and distributed without an approved application.

The product is adulterated under of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act) in that it is a new animal drug that is unsafe within the meaning of Section 512 of the Act.

"Cycle Pro Pregnant Mare Serum" is a new animal drug as defined under Sections 201(g) and (p)(1) of the Act. A new animal drug may not be legally marketed unless it is the subject of an approved New Animal Drug Application (NADA). New Animal Drug Applications may be approved on the basis of adequate scientific data that the applicant submits as evidence of the safety and effectiveness of the product. You do not have an approved NADA for your product. You can find guidance for industry concerning NADA submission at www.fda.gov/cvm.

This described violation of the law is not intended to be an all-inclusive list of possible deficiencies in your manufacturing and distribution of new animal drugs. In Title 21 Code of Federal Regulations (21 CFR), Parts 210 and 211, are the good manufacturing practices that must be followed by firms that manufacture, process, package and/or hold drugs. These are available for review at the National Archives and Records Administration website at www.access.gpo.gov/nara/cfr. It is your responsibility to ensure compliance to each of the requirements of the Act and implementing regulation.

Mr. Doug Robertson, Owner
Equine Serum Products, Inc.
February 21, 2002
Page 2

You should take prompt action to correct this deficiency. Failure to do so may result in further FDA enforcement action without further notice. Possible actions include but are not limited to the seizure of product and/or injunction.

Please send your response to this office, within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the identified deficiency including an explanation of each step being taken to prevent the recurrence of this and similar violations. Your response should be directed the Ralph J. Gray, Compliance Officer.

Sincerely,


Charles W. Sedgwick
District Director
Kansas City District Office