



DEPARTMENT OF HEALTH AND HUMAN SERVICES

m305len

Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

April 18, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref. KAN 2000-013

Mr. Thomas M. Spaeth, Manager
Kubus, Inc.
7019 T. Gabbert Drive
Pleasant Valley, MO 64068

Dear Mr. Spaeth:

During an inspection of your firm our Investigator found you to be importing and distributing ~~two new animal drugs~~ an artificial insemination aid. These products are New Animal Drugs as defined by Section 201(v)(1) of the Federal Food, Drug and Cosmetic Act (the Act) in that these drugs affect the structure or function of the body of animals, other than man. A new animal drug may not be legally marketed unless it is the subject of an approved New Animal Drug Application (NADA). NADAs may be approved on the basis of adequate scientific data obtained through controlled studies in which the applicant submits evidence of safety and effectiveness of the product (Section 512 of the Act).

These two identified new animal drugs are adulterated within the meaning of Section 501(a)(5) of the Act in that they are unsafe within the meaning of Section 512 of the Act in that neither product is the subject of an approved NADA in accordance with the requirements of Title 21 Code of Federal Regulations, Part 514 (21 CFR 514).

Your promotional literature and technical bulletins meet the definition of labeling, as defined in Section 201(m) of the Act. This product labeling and your direct product labels contain numerous claims that cause your products to be new animal drugs. Claims such as "myometrial activity stimulant", "exerts control on bacterial contamination", "microbiological control" and "sensitization effect on endometrium" are structure/function claims that cause your products to be new animal drugs.

We have enclosed 21 CFR 510, New Animal Drugs and 21 CFR 514, New Animal Drug Applications for your information and assistance in responding to this letter. We also refer you to review New Animal Drug and New Animal Drug Application guidance located on the Center for Veterinary Medicine's internet homepage <http://www.fda.gov/cvm>.

Mr. Thomas M. Spaeth, Manager
Kubus, Inc.
April 18, 2000

You must take prompt action to correct these violations. Failure to promptly correct the violations may result in enforcement actions being initiated by the Food and Drug Administration without further notice. This includes, among other possible sanctions, seizure of illegal product and injunction against the distributor of illegal products.

We would like to remind you the products entered from your manufacturer are still under detention and cannot be distributed until the resolution of this issue.

Please notify this office within fifteen (15) working days of receipt of this letter of the specific steps you will take to correct the violation. Please address your response to Ralph J. Gray, Compliance Officer of this office.

Sincerely,


John W. Thorsky
Acting District Director
Kansas City District Office

Enclosures

cc: Mr. Santiago Martin Rillo, Owner
Kubus SA
20 Pol Ind Europolis
28230 Las Rozas
Madrid, Spain

Ms. Jennifer Atterbury
Morrison & Hecker
2600 Grand Avenue
Kansas City, MO 64108-4606