DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94823d

June 24, 2004

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville MD 20852-1448

CBER-04-010

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Gloria Dodd, DVM
Everglo-Natural Veterinary Services, Inc.
P.O. Box 1242
Gualala, CA 95445

Dear Dr. Dodd:

The Food and Drug Administration (FDA) has reviewed your website at Internet address www.holisticvetpetcare.com and has determined that West Nile Virus Nosode Vaccine 30C and West Nile Virus Nosode Vaccine 30 mL Injectable are being promoted for conditions that cause the products to be drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) [21 USC 321(g)] and biologics, as defined in section 351(i) of the Public Health Service Act (PHS Act) [42 USC 262]. West Nile Virus Nosode Vaccine 30C and West Niles Virus Nosode Vaccine 30 mL Injectable are considered to be drugs because the therapeutic claims as shown on your website establish the products' intended use as drugs.

Please be advised that in order to introduce or deliver for introduction a biologic into interstate commerce, a valid biologics license must be in effect. Such licenses are issued only after a showing of safety and effectiveness for the product's intended use. Under section 505(i) of the FD&C Act, biologic products in the development stage may be distributed for clinical use in humans only if the sponsor has submitted to FDA an investigational new drug application (IND) that is in effect as specified by regulation (21 CFR Part 312). Based on a review of our files, FDA has no information that your product is the subject of an approved biologics license application (BLA) or investigational new drug application (IND). Therefore, your shipment of a product for which a valid BLA or IND is not in effect and which is at variance with the provisions of 21 CFR Part 312, represents violations of the PHS Act and the FD&C Act, and may result in the Agency seeking such relief as provided by law.

Background

West Nile Virus Nosode Vaccine 30C and West Nile Virus Nosode Vaccine 30 mL Injectable are drugs under section 201(g) of the FD&C Act. Examples of claims observed on your website include:

- "...to help stimulate immunity to this devastating and sometimes fatal disease in people and horses;" and
- "THIS VIRUS IS SWEEPING THE NATION, SPRED BY WILDBIRD/MOSQUITO POPULATIONS. Comes with full directions for administration to people and horses."

Your website provides a mechanism for purchasing the products through the site. Specifically, the website checkout page provides shipping to addresses within the United States. Further, the website checkout page provides the price for Homeopathy – West Nile Virus Nosode Vaccine 30C as $89.95 and for Homeopathy – West Nile Virus Nosode Vaccine 30 mL injectable as $149.95.

False or Misleading Information

The information on your website is false or misleading. For example, your website makes effectiveness claims, but it lacks adequate descriptions of the risks, warnings, and contraindications of your products. Consequently, your products are misbranded under sections 502(a), 502(f)(1), and 201(n) of the FD&C Act, and are marketed in violation of sections 301(a) and 301(b) of such Act.

Failure to Require Prescription

You have failed to require that your products be dispensed under a prescription from a duly licensed practitioner. Therefore, your products are misbranded under section 503(b)(1) of the FD&C Act, and are marketed in violation of sections 301(a), 301(b), and 301(k) of such Act.

Failure to Register Your Products

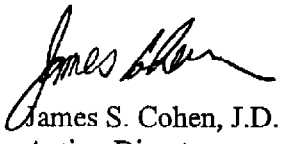
You have failed to register your drug establishment and list your products pursuant to section 510 of the FD&C Act. Consequently, your products are misbranded under section 502(o) of the FD&C Act, and are marketed in violation of sections 301(a) and 301(p) of such Act.

For the reasons cited above, you should immediately discontinue any website offer to sell West Nile Virus Nosode Vaccine 30C and West Nile Virus Nosode Vaccine 30 mL Injectable and remove from your website all other promotional materials for products that contain the same or similar violative presentations.

This letter is not intended to be an all-inclusive review of your website and products your firm may be marketing. It is your responsibility to ensure that all products marketed by your firm are in compliance with the FD&C and PHS Acts and their implementing regulations. You should take prompt action to correct the violations noted above. Failure to correct these violations promptly may result in regulatory action such as seizure and/or injunction without further notice.

Please notify this office in writing within 15 working days of receipt of this letter of any steps you have taken or will take to correct the noted violations and to prevent their recurrence. If the correction action(s) cannot be completed within 15 working days, state the reason for the delay and the time within which the correction(s) will be completed. Your response should be sent to the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, HFM-600, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, Attention: James S. Cohen, Acting Director, Office of Compliance and Biologics Quality.

Sincerely,



James S. Cohen, J.D.
Acting Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Enclosure:
Internet website pages