U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Canine Care 10/23/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
PHILADELPHIA DISTRICT
900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4390

WARNING LETTER

15-PHI-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 23, 2014

Dr. Jonathan Nyce
CanineCare.us, LLC
3422 Mill Road
Collegeville, PA 19426-1510

Dear Dr. Nyce:

This letter concerns the marketing of the products Tumexal Capsules, Tumexal Liquid, and Tumexal Transdermal by your firm CanineCare.us, LLC. The U.S. Food and Drug Administration (FDA) reviewed your product labeling and your website at the internet address www.caninecare.us, where you promote and sell the products.

We have determined that your products are drugs as defined by section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act ("the Act") [21 U.S.C. § 321(g)(1)(B)], as the products are intended for use in the mitigation, treatment, or prevention of disease in animals. As discussed below, these productsare unapproved new animal drugs and your marketing of them violates the Act.

Statements on your website and product labeling that establish these intended uses of your products include, but are not limited to, the following:

- "…Tumexal™ is effective against a wide array of canine cancers."
- "In fact, Tumexal™ will almost always restore a cancer-stricken dog's appetite, spirit and energy!"
- "Tumexal™ blocks canine cancer growth by restoring the activity of the p53 tumor suppressor pathway."

The above referenced products are only intended to be a sampling of the violative products you are currently marketing. Similarly, the above referenced claims are only intended to be a sampling of statements that demonstrate the intended uses of your products.

Because your products are intended to mitigate, treat, or prevent disease in animals, they are drugs within the meaning of section 201(g)(1)(B) of the FD&C Act [21 U.S.C. § 321(g)(1)(B)]. Further, these products are new animal drugs, as defined by section 201(v) of the FD&C Act [21 U.S.C. § 321(v)], because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling.

To be legally marketed, a new animal drug must have an approved new animal drug application, conditionally approved new animal drug application, or index listing under sections 512, 571, and 572 of the FD&C Act [21 U.S.C. §§ 360b, 360ccc, and 360ccc-1]. Your products are not approved or listed by the FDA, and therefore the products are considered unsafe under section 512(a) of the FD&C Act [21 U.S.C. § 360b(a)], and adulterated under section 501(a)(5) of the FD&C Act [21 U.S.C. § 351(a)(5)]. Introduction of an adulterated drug into interstate commerce is prohibited under section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

This letter is not intended to be an all-inclusive review of your products and their promotion. It is your responsibility to ensure that all of your products are in compliance with the Act and its

implementing regulations. Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

You should notify this office, in writing, within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include any documentation necessary to show that correction has been achieved. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Ms. Robin M. Rivers, Compliance Officer, U.S. Food and Drug Administration, 900 U.S. Customhouse, 200 Chestnut Street, Philadelphia, Pennsylvania 19106. If you have any questions about this letter, please contact Ms. Rivers at (215)717-3076 or e-mail at **robin.rivers@fda.hhs.gov (mailto:robin.rivers@fda.hhs.gov)**.

Sincerely,
/S/
Anne E. Johnson
Acting District Director
Philadelphia District Office

cc: Dr. Jonathan Nyce
CanineCare. us, LLC
399 Arcola Road Suite 105
Collegeville, PA 19426

Dr. Jonathan Nyce
P.O. Box222
Fairview Village, PA 19409