DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 06 2010

I-011949-A-0000-OT

Nuovo Biologics L.L.C.
Attention: Jay E. Yourist, Ph.D.
CEO
P.O. Box 160471
Miami, FL 33116-0471

Re: Request to open an investigational new animal drug (INAD) file

Dear Dr. Yourist:

In response to your request dated July 1, 2010, we have opened an investigational new animal drug (INAD) file for PANAVIRA. PANAVIRA is proposed for use as a broad spectrum antiviral in dogs, cats, horses, and birds.

For administrative purposes, you have been assigned file number INAD 011949 for the above referenced use. Please reference this number in all drug shipments and correspondence with us concerning the drug while it is under investigational use.

NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION

Sections 511.1(b)(3) and (4) require the sponsor to maintain certain records and to submit specific information prior to each shipment or other delivery of the drug for clinical investigation in animals. The agency has a form (FORM FDA 3458) which you, as the sponsor, may use to report shipments for clinical trials. Three copies of the completed Notice of Claimed Investigational Exemption (NCIE) form should be submitted for each drug shipment. Alternatively, you may file the notice of the drug shipment electronically to us. Please refer to the Center's electronic submission information on our website at http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/default.htm.

You must maintain records showing the name and post office address of the investigator to whom the investigational new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of two years after such shipment and delivery. These records must be made available for inspection and copying upon our request.

INVESTIGATIONAL LABELING

The appropriate investigational labeling required under 511.1(a) or (b) must be affixed to your investigational drug product before shipping your drug product for studies conducted under 21 CFR 511.1(a) or (b), respectively. Affix the investigational label to each individual drug container.

ADDITIONAL COMMENTS

1. Use of an investigational new animal drug obligates you, as the sponsor, to comply with the requirements in 21 CFR Part 511. We recommend that you review those regulations for further information about your responsibilities.

2. Your investigational new animal drug must be manufactured, processed, packaged, and labeled in such a way as to maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to investigations made with the drug.

3. In order for us to complete our files, the disposition of all investigational animals and unused drugs must be reported to this office.

4. Promptly report to this office any adverse reactions that may suggest significant safety hazards.

5. In your INAD exemption request, you included several inquiries regarding the development of your product. We recommend that you request a presubmission conference to discuss the requirements for approval of your product.

6. Please submit a claim for a categorical exclusion from the requirement to prepare an environmental assessment (EA) or an EA as required under 21 CFR 511.1(b)(10) before you begin conducting 21 CFR 511.1(b) studies. If you feel that a categorical exclusion is appropriate, please claim an exclusion under 21 CFR 25.33(e). If you make such a claim, you must, in accordance with 21 CFR 25.15(a), state that to your knowledge no extraordinary circumstances exist which may significantly affect the human environment (21 CFR 25.21). If you do not feel a claim for a categorical exclusion is supportable, please prepare an EA and forward it to this office for review.

If you submit correspondence relating to this letter, you should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact Dr. Amy Omer, Supervisory Team Leader, at (240) 276-8336.

Sincerely,

Mary E. Allen, Ph.D.
Acting Director, Division of Therapeutic Drugs
for Non-Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine