DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 18 '97

Mr. Greg Hooper
Chief Executive Officer
National Registration Authority
for Agricultural & Veterinary Chemicals
1st Floor, Industry House, 10 National Circuit
Barton ACT PO Box E240
Queen Victoria Terrace
A.C.T. 2600 Australia

Dear Mr. Hooper:

The Center for Veterinary Medicine (CVM), as part of the US Food and Drug Administration, is pleased to cooperate with your government in facilitating the rapid exchange of documents and information related to the regulation of animal pharmaceuticals. CVM agrees that this cooperation should be based on mutual equality and benefit. Efforts should be directed toward issues of mutual interest and priorities for cooperation should be set accordingly. It is our understanding that cooperation between the CVM and the NRA should be continuously reassessed to take into account experience gained over time. Cooperation will include the specific initiatives described below:

The Center for Veterinary Medicine will make available copies of FOI summaries on all approved new animal drug applications.

The CVM will make available yearly updates on adverse drug event reporting.

When CVM discovers, during the course of inspection activities, or through other means, particular circumstances whereby an animal drug presents an imminent and serious danger to the public, CVM intends to communicate its findings to the NRA in accordance with 21 CFR 20.89.

Upon request from the NRA, CVM will consider the disclosure of the relevant portions of its assessment of a specific investigational new animal drug or new animal drug application. This disclosure will be in accordance with 21 CFR 20.89.

CVM intends to routinely provide copies of draft publicly available guidance documents to the NRA for comment. CVM will provide this information through electronic means whenever possible. Upon request from the NRA, CVM will consider the exchange of nonpublic, pre-decisional documents concerning FDA's regulations or other regulatory requirements in accordance with 21 CFR 20.89.

In return, the NRA agrees to make similar information available to the FDA.

CVM will consider temporary staff exchanges to enhance cooperation and communication between the CVM and the NRA. Where such staff have access to non-public information within FDA files, the relevant sections of 21 CFR 20.89 would also have to be complied with.

To help ensure that this information exchange initiative works well and meets our needs, CVM believes that it is important that, at appropriate intervals, and by mutual concurrence, a discussion or meeting take place to assess the activities outlined in this letter.

The FDA contact for these activities is as follows:

Dr. Sharon R. Thompson
Special Assistant to the Director
Center for Veterinary Medicine (HFV-3)
7500 Standish Place
Rockville, MD 20855
Phone (301) 594-1798
Fax (301) 594-1830
E-mail: STHOMPSO@BANGATE.FDA.GOV

This information exchange initiative should lay the groundwork for closer communication and cooperation between the CVM and the NRA on issues relevant to veterinary drug regulation. CVM recognizes that this cooperation will be subject to the domestic legal obligations and available resources of each party and may be terminated at any time by either party, upon notice to the other. We will be happy to proceed with this arrangement once we receive your letter specifying and acknowledging your concurrence. I am enclosing a copy of 21 CFR 20.89 for your information.

Sincerely yours,

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

Enclosure