November 23, 1988

Dear Sir or Madam:

On November 16, 1988, the President signed the Generic Animal Drug and Patent Term Restoration Act (copy enclosed). Among other things, it extends eligibility for the submission of abbreviated New Animal Drug Applications (ANADAs) to drug products first approved as New Animal Drug Applications (NADAs) after the 1962 Amendments to the Federal Food, Drug, and Cosmetic Act (the Act). Sponsors may submit ANADAs starting 60 days after enactment of the new law, or January 15, 1989.

The new Act requires that within 30 days of enactment each sponsor of a currently approved NADA submit to us patent and exclusivity information on these approved products. This letter provides preliminary guidance on the listing of drugs that are approved and the procedures you should follow for submitting patent and exclusivity information. We are in the process of preparing additional interim guidance on how FDA intends to implement the new statute, which we intend to make available within 90 days. During this initial implementation phase, FDA will follow existing regulations, policies and procedures, except as noted below, or where the statutory language dictates otherwise.

In all cases where a certification, statement, or waiver is to be submitted, the certification, statement, or waiver should be signed by the applicant or patent owner, or by its attorney, agent or other authorized official. It is the responsibility of applicants and patent owners to instruct their employees as to the scope of their duties and whether or not each is authorized to make any required certification or statement.

Submission of Patent Information by NADA Holders

Language added to section 512 of the Food, Drug, and Cosmetic Act (the Act) by section 102 of the Generic Animal Drug and Patent Term Restoration Act requires holders of approved NADAs, and NADA applicants, to submit certain patent information. The information that is required to be submitted includes the patent number and expiration date of any effective patent which claims the new animal drug for which the application was filed or a method of using such drug. The information that is to be submitted includes information on formulation patents and composition patents for the new animal drug product. However, information should not be submitted on process patents (patents that cover a method of manufacturing). A suggested format for the submission of this material is attached.

The relevant patent information must be submitted as follows:

- Holders of currently approved NADAs for drugs for which patents have been issued must submit the required patent information within 30 days after enactment of the generic act, i.e. by December 16, 1988.

- Holders of currently approved NADAs for drugs for which patents have not been issued but for which patents are issued in the future must submit the required patent information within 30 days after the issuance of the patents.

- Sponsors of pending NADAs for drugs for which patents have been issued, and sponsors of pending NADAs for drugs which patents are issued prior to approval, should submit the required patent information prior to approval.

- Sponsors of NADAs that are submitted in the future for drugs which patents have been issued must submit the patent information with the application.

- Sponsors of NADAs that are submitted in the future for drugs for which patents have not been issued at the time of NADA submission, but that are issued prior to approval, should submit the patent information prior to approval.

- Sponsors of NADAs that are approved in the future for drugs for which patents are issued after approval must submit the required patent information within 30 days after the issuance of the patents.

The procedures described above also apply to supplemental NADAs for changes that are covered by patents or become the subject of patents that are issued in the future.

The patent information that is to be submitted must be filed in a supplement to the approved or pending NADA. However, we also request that a copy of the patent information be sent to the Office of New Animal Drug Evaluation (see below). All patent information that is submitted with respect to approved applications will be published in the list of currently approved drugs, and will be updated in the monthly supplements to the list. FDA will not publish patent information prior to the approval of the NADA or supplemental NADA.

If the patent owner is different than the NADA holder or applicant, the submission should state the name of the patent owner as well as that of the applicant or NADA holder. If the patent owner or NADA holder or applicant does not reside or have a place of business in the United States, the submission should also name an agent of each non-resident patent owner and NADA holder applicant in the United States authorized to received notice under section 512(n)(1)(H).

If information on a patent is not timely filed, e.g., is filed more than 30 days after enactment of the Act or more than 30 days after issuance of the patent, the agency could refuse to publish the untimely information, or (as provided by new section 512(d)(1)(D)) could withdraw the NADA if the patent holder failed to respond within 30 days to a notice from the agency. FDA has conclude, however, that while Congress clearly intended to encourage timely filing, a less severe penalty for late filing would effectuate Congress' intent without eliminating all statutory patent protection or withdrawing the NADA itself. Therefore, if an NADA applicant files required patent information on an untimely basis, FDA will publish the untimely information but will not require generic applicants with pending applications, who have previously submitted a correct certification, to re-certify as to the new patent information. Only applicants who submit ANADA's after the filing of the patent information will be required to submit a certification as to that patent.

In all cases, the date that FDA receives the patent information will be considered the date the information was filed.

Exclusive Approval for Certain Drugs

The new legislation establishes various periods of time during which ANADAs for certain products may not be submitted or approved if a pioneer application qualifies for exclusivity. Exclusivity applies to applications that are approved following enactment of the new law. If in the future you believe one or more of your approved products qualify for such exclusive approval status, please notify us promptly upon approval of the application. We plan to publish these and all other data required by the statute in supplements to the approved drug list.

The List of Currently Approved Drugs

The new legislation provides that within 60 days of enactment, FDA must make publicly available a list of all drugs which have been approved for safety and effectiveness before the date of enactment. The agency must update the list every 30 days. To comply with this requirement, FDA will initially file a copy of the list with the Dockets Management Branch and publish a notice of availability in the FEDERAL REGISTER. Supplements to the list will be used to explain in more detail how this requirement is being implemented, and to publish required patent information and information on periods of exclusivity for submission or approval of ANADAs for specific products. Copies of the list and its supplements may be obtained from the Industry Information Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

Patent Certification for ANADAs

In addition tot he other requirements listed in the new law, all ANADA applicants must, as outlined in new section 512(n)(H) of the Act, certify regarding the patent status of the listed drugs referred to in the NADAs. All ANADAs must contain patent certification information. If this patent information is not included in the ANADA, the application will be considered incomplete. For all relevant patents on the approved drug, an applicant must certify one of the following:

(1) no patent information has been filed under subsection (b)(1) or (c)(3);
(2) the patent has expired;
(3) the date on which the patent will expire; or
(4) the patent filed is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

If the applicant seeks approval for a method of use which is not claimed in a method of use patent for the listed drug, the applicant must certify that the method of use patent does not claim the use for which the applicant seeks approval.

Where to Submit Patent and Exclusivity Information

As previously explained this information is to be filed in a supplement to an approved or pending NADA. Additionally, to expedite the compilation and the publication of the patent and exclusivity information by the Agency, currently approved NADA holders are requested to submit patent and exclusivity information to:

Office of New Animal Drug Evaluation (HFV-100)
Center for Veterinary Medicine
5600 Fishers Lane
Rockville, Maryland 20857

In response to industry requests we are enclosing a suggested format for the submission of this patent and exclusivity information.

Additional Information

For general question regarding the ANADA aspects of the new legislation contact:

Dr. Richard B. Talbot
Office of New Animal Drug Evaluation
Center for Veterinary Medicine
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-4313

For information on the patent extension aspects of the new legislation contact:

Charles VanHorn
Box 8 Patent and Trademarks Office
Washington, D.C. 20201
Phone: (703) 557-4035

or

Ronald Wilson
Director, Health Assessment
Policy Staff, (HFV-20)
Office of Heaalth Affairs
5600 Fishers Lane
Rockville, Maryland 20857
Phone: (301) 443-1382

FDA plans to issue proposed procedural regulations to implement the new law and will, at that time, comply with applicable provisions of the Paperwork Reduction Act.

We will keep you informed of additional guidance through written communication and through meetings of appropriate legal and professional associations on a continuing basis. We welcome your input and interest.

Sincerely yours,

/s/

Gerald B. Guest
Director, Center for
Veterinary Medicine

Suggested Format for Patent and Exclusivity Information

1) NADA Number
2) Applicant Firm Name
3) Approval Date
4) Trade Name
5) Active Ingredient(s)
6) Strength(s)
7) Dosage Form
8) Route of Administration
9) Exclusivity – Date
   first ANADA could be approved and length of exclusivity period
10) Applicable patent
    numbers and expiration date of each *
11) Identification of U.S. Agent if held by foreign person

* The above information should be supplied for each product.