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Central Research

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December 15, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. **99D-1651**

Dear Sir or Madam:

This letter is written to respond with comments regarding the Food and Drug Administration, Center for Veterinary Medicine's (CVM's) draft guidance entitled "Chemistry, Manufacturing and Controls Changes to an Approved NADA or **ANADA**."

Pfizer Central Research, Groton, CT is aware of and supports the Animal Health Institute industry position regarding this guidance. In the event the current draft guidance proceeds forward with the current format and content, Pfizer Central Research has the following comments and/or suggestions:

1. Pfizer Central Research suggests the CVM guidance be revised to agree with the revised Center for Drug Evaluation and Research (CDER) guidance document "Changes to an Approved NDA or **ANDA**" in all aspects except as indicated below and with particular regard to references and/or clarifications of the guidance's application to drug substances.
 - a. Section VI., Sites, **B. Major Changes**: retain CVM's statement that subsequent manufacturing site transfers to a different site for aseptic processing can be submitted in a Changes Being Effected – 30 days supplement.
 - b. Section VII., Manufacturing Process, **B. Major Changes**: retain CVM's statement that subsequent replacements of a Class 100 aseptic fill area with a barrier system can be submitted in a Changes Being Effected – 30 days supplement.
 - c. Section IX., Package, Section A. General: retain CVM's listing of examples of major changes as there has been confusion in industry regarding these types of changes,
 - d. Section X., Miscellaneous Changes, Section B. Moderate Changes: retain CVM's provision to allow changes in components or composition that have been approved in corresponding human drug products.

99D-1651

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- e. Section X., Miscellaneous Changes, Section C.: disregard **CDER's** inclusion of a listing allowing the updating of stability protocols to comply with ICH storage conditions as animal health products are subject to unique storage conditions in the field which may not warrant compliance with **VICH** stability storage conditions and may require a higher level of review.
- f. Regarding CDER's inclusion of a section concerning Labeling changes: due to the complexity of this issue, a separate guidance may be warranted.

Please accept these comments in your review of the above-mentioned CVM draft guidance document. If you have any questions regarding these comments, please contact me at **860-441-3242**.

Sincerely,

A handwritten signature in black ink, appearing to read "J. F. Taylor". The signature is written in a cursive style with a large initial "J" and a long horizontal stroke at the end.

Joseph F. Taylor
Director, Analytical Research and Development
Pfizer Central Research

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