DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FA-305

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Mr. John H. Carter, III
Committee on Safe & Effective Aquarium Drugs
1701 Waters Edge Drive
Newark, Delaware 19702

Re: Docket No. 93P-0396

Dear Mr. Carter:

This acknowledges receipt of your letter dated June 27, 2003 addressed to Dr. Stephen Sundlof. You requested the status of the citizen petition you submitted to the Food and Drug Administration (FDA), on October 19, 1993, on behalf of the Committee on Safe & Effective Aquarium Drugs (COSEAD) concerning new animal drug applications (NADA's) for current and future products marketed for the diagnosis, control, and treatment of diseases in freshwater and marine aquariums.

On July 15, 1994, FDA provided a detailed interim response which served as a final response to several aspects of your request. The agency deferred final comment on the two remaining issues regarding NADA's for freshwater and marine aquarium products (as described above) and associated current good manufacturing practices (CGMP's). The letter explained that at the time, FDA was in the process of evaluating the need for an overall enforcement policy for aquarium fish and ornamental fish drugs, including compliance with relevant CGMP's.

At present, FDA is working on a response that gives careful consideration to the significant scientific and policy issues raised by your citizen petition. We anticipate that FDA's response to your citizen petition will be sent to you by the end of the year.

Sincerely yours,

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

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