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# LETTERS TO AFA

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## Concerned about FERVAC-D

This letter is in response to your articles on canine distemper virus (C.D.V.) in the May/June 1999 issue of *The American Ferret Report* [1999;10(3):11–13]. It seems that most vaccine reactions occur in the spring and summer. This could be because most people vaccinate during these seasons—they are getting ready for the show and breeding season, last year's kits are due for their boosters, and new spring kits are being given their initial series of shots. Vaccination tapers off in the fall and winter.

The common factor of these reactions that A.F.A. is looking for is that nearly all ferrets that experience a reaction have been vaccinated with FERVAC-D (United Vaccines Inc.). The article by Dr. Ann Gillis stated that although GALAXY-D (Schering-Plough) is commonly used for ferrets, it has not yet been tested and proved in laboratory studies to be effective in preventing C.D.V. in ferrets. Although this is true, GALAXY-D has certainly been tested and proven in actual use.

FROMM-D (Solvay) was changed to GALAXY-D in the spring of 1992. We all were told that only the name of FROMM-D had been changed because the company had been bought out. This was the same year FERVAC-D was approved by the U.S. Department of Agriculture (U.S.D.A.) and the same year of the big C.D.V. outbreak.

Most of us tried FERVAC-D because of its U.S.D.A. approval [for use in ferrets]. After many of our ferrets experienced serious reactions, including several deaths, we decided to use GALAXY-D. It was a year or more before we found out that the formula of GALAXY-D had also been changed. This was when the A.F.A. decided to allow only those ferrets vaccinated with FERVAC-D at their

shows. Because GALAXY-D had already been working to prevent C.D.V. without side effects, some of us decided to put our ferrets first and not attend any functions that did not allow us a choice of which vaccine we could use. Other people more interested in winning ribbons and selling ferrets gave in and started using FERVAC-D.

### Most of us tried FERVAC-D because of its U.S.D.A. approval.

The number of adverse reactions increased along with more C.D.V. outbreaks. Even vaccinated ferrets contracted C.D.V. There was a ridiculous statement made by a ferret owner in one article [*A.F.R.* 1996;7(6):10] that suggested that a ferret's color may have caused FERVAC-D to fail. Ferrets vaccinated with GALAXY-D were not contracting C.D.V. no matter what color they were.

As a ferret breeder and the owner of a ferret shelter, I use 200–300 vaccines a year. In the seven years GALAXY-D has been available, I have had only three reactions from it; they were all mild and did not require veterinary intervention. I was using GALAXY-D in 1992 when the big C.D.V. outbreak occurred. I lost only those kits that were too young to vaccinate. My adult ferrets and even those kits whose vaccination series had just begun survived. A year and a half ago, I received a rescue ferret that had C.D.V. She was here a week before showing signs of C.D.V. None of my ferrets, including kits as young as three months old, were affected, and I have the colors mentioned in that article.

Those of us who continue to use GALAXY-D do so with the confidence that our ferrets are protected not only from C.D.V. but also from vaccination-related reactions. We can vaccinate anytime of

the day or night, weekends or holidays. We do not have to sit in the veterinarian's office or pretreat with unnecessary drugs. I am tired of hearing about laboratory testing and U.S.D.A. approval and from owners whining about reactions. GALAXY-D has been tested in real life situations, not just in some sterile laboratory.

I wonder what the results would be if the A.F.A. did an anonymous survey of the people who attend their shows asking how many would switch back to GALAXY-D if the A.F.A. would once again accept it. FERVAC-D may be politically correct because it is U.S.D.A. approved, but it is morally wrong because of the pain and suffering it causes ferrets. If everyone who really cares about their ferrets would push Schering-Plough to get GALAXY-D U.S.D.A. approved, we could put an end to this whole problem.

*Linda Harrah, Ferret Sense  
Buckeye Lake, Ohio*

## FERVAC-D Safe Compared with Other Vaccine Products

Dear Ms. Harrah,  
Thank you for voicing your opinion on the vaccines used to prevent C.D.V. in ferrets. We appreciate your concerns, which have been shared by many, regarding the alleged high number of adverse reactions of ferrets to the vaccine licensed by the U.S.D.A., FERVAC-D.

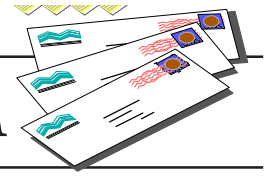
The information received by the U.S.D.A. on this product regarding adverse events, however, does not indicate a particularly high number of adverse reactions to this product, nor a batch-to-batch problem, when compared with other veterinary vaccine products.

The A.F.A. acknowledges that there has

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been much discussion and consternation in the ferret community over the years regarding what appears to be an unacceptable number of adverse events, whether real or perceived, associated with FERVAC-D. The ferret community must remember that all vaccines, whether for ferrets, dogs, or humans, have inherent risks. Vaccines are derived from killed or modified live organisms that, in the natural state, would actually produce the serious or life-threatening conditions they are made to prevent. This makes vaccines complicated and expensive to manufacture.

Vaccination tricks the body into thinking that it has recognized an infectious agent. This causes the body to produce an immune response—making antibody or stimulating the “memory” of special cells (lymphocytes)—that will protect the body in the event of an actual exposure to the natural infection. Often the vaccine reaction mimics a real infection but to a lesser extent. For these reasons, mild reactions to vaccines are to be expected. It is important, however, to be prepared to treat a serious or life-threatening reaction when vaccinating any animal or person. Most vaccine reactions occur within the first 15–60 minutes following vaccination, but there are some delayed reactions that may occur up to 72 hours later. Rarely are there long-term effects.

Regarding FROMM-D and GALAXY-D, several points must be made. The decision to remove FROMM-D from the U.S. market was made by the company. Both FROMM-D and FERVAC-D are derived from chick embryo cell lines; whereas GALAXY-D is produced from a monkey cell line. GALAXY-D was developed and is being marketed as a C.D.V. vaccine for dogs. As part of required, routine safety testing conducted on any C.D.V. vaccine, this product was evaluated for toxicity in domesticated

ferrets because ferrets are more sensitive to C.D.V. than dogs. Safety testing was not performed to determine vaccine reaction rates, which is the concern ferret owners have with FERVAC-D.

## **A.F.A. is unaware of any adequate efficacy testing for GALAXY-D.**

Safety testing by law must measure only how many animals survived a specified amount of time after the injection. For example, all human vaccines are safety tested in guinea pigs. The animals are injected with the vaccine, and if they stop gaining weight, the vaccine is rejected. This type of test has no relevance to the safety of a vaccine used to prevent a species virus.

Efficacy testing, however, requires that ferrets be challenged with the viral infection within one year following immunization. The regulations require that the vaccine must prevent infections in the species of interest in a specified percentage of animals (Title IX Code of Federal Regulations Section 113.300 and 113.306). A.F.A. is unaware of any adequate efficacy testing conducted on or submitted to U.S.D.A. concerning GALAXY-D.

A.F.A. has been studying the problem of vaccine reactions in ferrets and has met with both U.S.D.A. and U.S. Food and Drug Administration officials to discuss the problems of postmarketing surveillance and data collection for the ferret vaccines. A.F.A. is also undertaking its own evaluation of the problem. Currently postmarketing surveillance of veterinary vaccines is voluntary, that is, not required by law or regulation, although U.S.D.A. has asked vaccine manufacturers to provide a summary of the reports they receive on their marketed products. This situation is undergoing reevaluation by the Federal gov-

ernment. In addition, the most recent A.F.A. survey of veterinarians showed that our member veterinarians have seen ferrets react seriously to both GALAXY-D and FERVAC-D.

Although no vaccine product is 100 percent reliable, A.F.A. is unaware of any documented case of C.D.V. in a ferret that had been adequately vaccinated with the currently licensed vaccine product. In the past, I have been personally made aware of at least one case of C.D.V. in a ferret properly immunized with FROMM-D.

With respect to the possibility of color influencing the rate of adverse reactions in ferrets, the A.F.A. and U.S.D.A. have no documentation of this occurring. Some kinds of reactions to vaccines and drugs do occur more frequently in certain populations, probably due to genetic or environmental factors, but this remains to be determined for ferrets.

A.F.A.'s loyalty to licensed or approved medical products has to do only with the completeness of their testing and reliability in the clinical setting. A.F.A. officers are required to sign conflict of interest disclosure statements, which are publicly available, and there is no conflict of interest regarding A.F.A. officials and any currently marketed product.

Finally, the A.F.A. continues to seek out good products for ferrets. A.F.A. is constantly discussing new product lines with manufacturers and is particularly concerned with products that are meant to protect ferrets against highly contagious and deadly diseases, such as C.D.V. Until such vaccine products undergo appropriate testing, A.F.A. cannot support their use in ferrets because the risk to others is just too great.

*Dr. Freddie Ann Hoffman, M.D.  
A.F.A. Health Affairs Committee*