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FDA Decision on Selenium

April 11, 1995

FDA has decided that the Agency will generally not object to the manufacture, marketing, or use of feed with selenium supplementation of 0.3 part per million (ppm) in complete rations for species such as horses, rabbits, and goats. This is an increase from 0.1 ppm in the complete ration for these animals that the Agency had permitted in the past. This covers only sodium selenite or selenate supplementation to animal feed or feed supplements.

In 1987, FDA published a food additive amendment which permitted animal feeds for chickens, swine, turkeys, sheep, cattle, and ducks to contain supplemental selenium at a rate of 0.3 ppm. In addition, in 1989 FDA approved an osmotic selenium bolus for use in beef and dairy cattle. The bolus provided 3 mg of selenium per day. These levels are listed in Title 21, Part 573.920 of the *Code of Federal Regulations.*

This regulation did not apply to other animal species such as horses, rabbits, and goats. However, the FDA stated it would not object to supplementation with either sodium selenate or selenite at a level of no more than 0.1 ppm in the complete ration to assure the selenium requirement of these other species was met.

On September 13, 1993, FDA announced that the 1987 amendment of the food additive regulation increasing permitted levels of supplemental selenium in animal feeds for chickens, swine, turkeys, sheep, cattle, and ducks had been stayed. The Agency took this action because FDA concluded that the environmental assessment and "finding of no significant impact" for the action were inadequate. In addition, the 1989 amendment for the osmotic bolus was also stayed.

In 1994, Congress and the President responded to the FDA's stay of the 1987 amendments to the selenium food additive regulation. In FDA Appropriations legislation, signed by President Clinton on September 30, 1994, an amendment was included that suspended that stay until December 31, 1995. A second action, which was included in the Federal Crop Insurance Reform Act signed on October, 13, 1994, states that the FDA shall not implement or enforce the stay unless the Commissioner of the FDA finds that selenium supplementation at 0.3 ppm in complete diets is not essential to maintain animal health, is not safe to animals consuming the additive or humans consuming edible portions of selenium-supplemented animals, is not effective to promote normal growth and reproduction, and that the manufacture and use of supplemental selenium cannot be reasonably controlled by adherence to current good manufacturing practice requirements. As a result of these actions, FDA's stay of the 1987 amendments is no longer in effect.

In light of the current status of the selenium regulation and to facilitate a similar use of selenium for all animal species, FDA has reevaluated its earlier position. The Agency has decided that it will not usually support regulatory action against individuals who manufacture, market, or use feed with up to 0.3 ppm of supplemental selenium using sodium selenite or selenate for those animal species not listed in the selenium regulations such as horses, rabbits, and goats. Also included will be feed supplements intended to be added to the feed by the consumer or fed individually with adequate directions for use so that the amount provided will not exceed 0.3 ppm on a complete-ration basis. Questions concerning this position may be directed to CVM's Division of Animal Feeds at the following address: FDA, Center for Veterinary Medicine, Division of Animal Feeds, 7500 Standish Place, HFV-226, Rockville, MD 20855, or telephone at (301) 594-1724.

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