The state veterinarian has been informed that some market lamb youth have been using an unapproved product (melatonin) in project animals. Please share the information below widely so we can stop this ILLEGAL activity.

Although melatonin is available over the counter as a sleep aid/regulator for humans, it is classified as a dietary supplement and therefore not approved by the Food and Drug Administration (FDA). The FDA does not approve or license dietary supplements; it only tests them for safety (no contaminants, etc.).

Melatonin is a hormone. It is approved for use in food animals in other countries, but in the U.S., it is only approved for use in mink “to accelerate the fur priming cycle.” See the info below from the FDA site; it specifically says “do not use in food-producing animals.”

Because melatonin is not approved for use in food animals in the U.S., no withholding times have been established for it. This means the residue tolerance level is ZERO. The Food Animal Residue Avoidance Database says no recommendations can be made regarding withholding times to achieve zero residue in animals that have been treated with this hormone.

Do not confuse this issue with extra-label drug use (ELDU). ELDU is permissible under the guidance of a farm’s veterinarian in specific circumstances (details at https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/ucm085377.htm). A critical aspect of ELDU: “it is limited to circumstances when the health of an animal is threatened, or suffering or death may result from failure to treat. This means extralabel use to enhance production is not permitted.” Uninformed or unscrupulous sheep producers use melatonin to enhance wool/hair growth and to calm excitable animals; these are production issues (and “show animal” production issues at that), not health issues, so this use does not fall under legal ELDU. Additionally, ELDU only pertains to medications approved by the FDA for animals or humans; melatonin is not approved by the FDA. For a comprehensive and up-to-date resource of FDA-approved medications, see https://animaldrugsatfda.fda.gov/adafda/views/#/search.

Summary
- Melatonin is not approved for use in food animals in the U.S.
- Using melatonin in food animals violates federal food safety regulations
- Using melatonin never qualifies for legal extra-label drug use
- Penalties and incarceration are possible when food safety regulations are violated
- It is critical for food animal producers to use credible sources to thoroughly investigate the legality of any products they use in or on their livestock
- Use of unapproved medications threatens the reputation of all youth-grown food animal products, risks exclusion of youth market animals from processing plants, and endangers the future of youth livestock market sales

Please make sure all 4-H youth, leaders, volunteers, and fair sheep superintendents receive and understand the contents of this message. Contact Randy Williams if you have any questions.

Randy Williams | randy.williams@wsu.edu | 509.869.1818

WSU Extension programs are available to all without discrimination.