Pfizer To Suspend Sale Of 3-Nitro (Roxarsone) In The United States

Action Called a Prudent Step

Madison, N.J., June 8 - Pfizer Inc.’s Alpharma LLC subsidiary has decided to suspend sales in the United States of 3-Nitro® (Roxarsone), a feed medicine used primarily in poultry production. Pfizer is taking this action in response to a request by the U.S. Food and Drug Administration (FDA) based on a recent study by the Agency. This study used a new method of testing for very low levels of inorganic arsenic in poultry tissue. The study found that the use of 3-Nitro results in extremely low residue levels of inorganic arsenic in the liver of treated chickens but levels higher than those found in chickens raised without the product. This extremely low level is equivalent to the amount of inorganic arsenic found in an eight-ounce glass of drinking water.

FDA agency officials stressed that there is no imminent public health risk from eating chicken treated with 3-Nitro. According to the FDA, even in the context of this recent data, there is no need for people to alter their consumption of chicken. Low levels of inorganic arsenic occur naturally in a wide range of commonly eaten foods that are considered safe to eat, including meats, fish, vegetables, grains, and legumes.(1)

Pfizer views its decision to suspend sales as prudent in light of the Agency’s request that Pfizer assist in removing an avoidable
exposure to very low levels of inorganic arsenic from eating liver from chickens treated with 3-Nitro. As agreed to by FDA, the 3-Nitro sales suspension will go into effect in early July. This action provides for maintained sales of the product for 30-days from the date of FDA announcement. Maintaining sales for this period is consistent with FDA’s view that there is no imminent risk to human health and will provide sufficient time for poultry producers to identify and transition to other treatment strategies. This approach will help assure that animal health and welfare needs are met.

Pfizer is working with FDA to examine further relevant scientific data regarding the use of this product in animals. Pfizer also continues to review the results of the study.

3-Nitro is indicated for combination use with certain other medications as an effective aid in the prevention of coccidiosis, the most common infection in poultry. 3-Nitro is also approved by the FDA to improve rate of weight gain and feed efficiency in poultry and swine. Its use in swine is negligible.

Pfizer is informing poultry producers and will help them identify therapy strategies to meet their needs during the suspension period. Pfizer is also communicating its decision to suspend sale of 3-Nitro in the U.S. to regulatory authorities in international markets where 3-Nitro is approved.

Poultry producers who have questions should contact Pfizer Veterinary Medical Information Product & Support at 800-366-5288. Consumers who would like more information may visit www.fda.gov.

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