JUL 20 1999

FINDING OF NO SIGNIFICANT IMPACT
and
Environmental Assessment

Addition of
Tylosin Tartrate Pellet to
Component® Implants

Ivy Laboratories, Inc.
Overland Park, Kansas

FOR PUBLIC DISPLAY

NADA - 110-315

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The Center for Veterinary Medicine has considered the potential environmental impact of this action and has concluded that this action will not have a significant impact on the quality of the human environment and that, therefore, an environmental impact statement will not be prepared.

Ivy Laboratories is requesting approval of supplements to the approved applications for Component® Implants containing various ingredients including testosterone, estradiol, progestorone and trenbolone. The supplements provide for the addition of a 29 mg pellet of tylosin tartrate to the ear implants of various Component® products. The testosterone, estradiol, progesterone and trenbolone acetate components of the product would qualify for a categorical exclusion under 21 CFR 25.33(a)(1) since these component have already been approved and their use would not increase. The 29 mg tylosin component has not been approved and under certain conditions its use will increase. The pellet is to act as a local antibacterial to prevent infections after implantation.

In support of the approval of the supplements, Ivy Laboratories has submitted an environmental assessment (copy attached) dated October 22, 1997. The EA indicates that the dosage of tylosin, computed on a daily basis, could result in the introduction of 0.6 mg/day of tylosin into the environment. Tylosin is currently approved for use in cattle feed. The proposed use of tylosin in the pellet is within the dosage already being administered in feed. Therefore, no increase in environmental introductions will occur as a result of the use of the pellet use in cattle, provided the cattle are not being fed tylosin. For cattle that are being fed tylosin, the increase in the amount of tylosin introduced into the environment represents 0.6 mg per day for 45 days. Relative to the 60 - 90 mg/day already being continuously introduced into the environment from the use of tylosin in feed, the 0.6 mg increase is not expected to result in a significant increase in environmental exposures or effects to organism in the environment.

The EA is adequate to determine that the proposed inclusion of tylosin pellet will not have a significant impact on the human environment.

4/14/98
Date

Director, Office of New Animal Drug Evaluation, HFV-100

Attachments: June 19, 1989 Environmental Assessment and attachment

Section 10: Environmental Assessment

1. **Date:** October 22, 1997

2. **Name and Address of Applicant:**
Ivy Laboratories, Inc.
8857 Bond Street
Overland Park, KS 66214

3. **Description of Proposed Action:**
Beef cattle commonly receive anabolic implants which are administered in the ear. The purpose of addition of a tylosin tartrate pellet to an implant is to act as a local antibacterial.

4. **Reasons this Action is not Expected to Cause an Environmental Impact:**
Addition of a pellet containing 29 mg tylosin tartrate to Component® brand implants is not expected to cause a significant environmental impact. Tylosin is already approved under 21 CFR 558.625 for use in the reduction in the incidences of liver abscesses in beef cattle at 60 - 90 mg per head per day fed continuously. The addition of tylosin in an ear implant at 29 mg could result in an increase in the daily introduction of tylosin into the environment of 0.6 mg per day over a 45 day period. The 0.6 mg per day represents an increase of only 0.6% (0.6 mg/90 mg x 100) in the use of tylosin, if tylosin is already being used in feed. Unless there is specific information to the contrary, we would assume that this small increase in use will not result in a significant environmental impact. If tylosin is not already being used as feed, the amount introduced from the proposed use (0.6 mg/day) in the implant is insignificant relative to the amount already being introduced into the environment from feed (i.e., 60 - 90 mg/day).

5. **Prepared By:**

Gary D. Hindman, Ph.D.
Bill Zollers, Ph.D.

6. **Signatures:**

Gary D. Hindman, Ph.D., Vice President & General Manager

Bill Zollers, Ph.D., Senior Project Manager