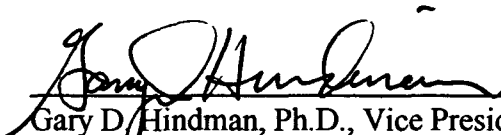


Section 10: Environmental Assessment

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% ($0.6 \text{ mg}/90 \text{ mg} \times 100$) 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