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Charlotte, North Carolina
September 15-17, 2016

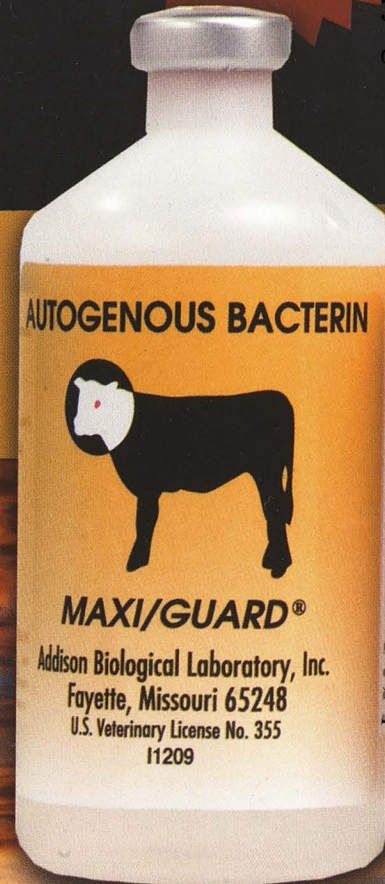
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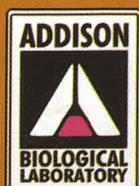
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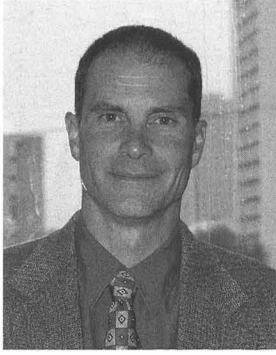
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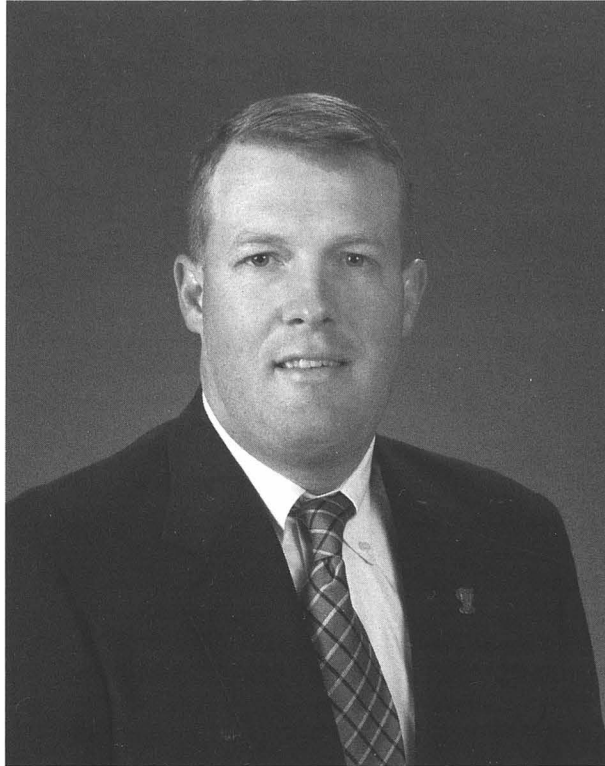
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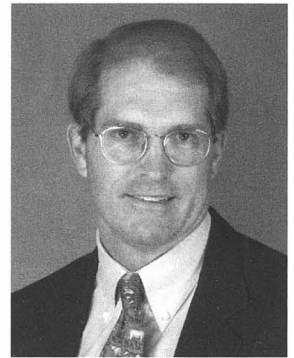
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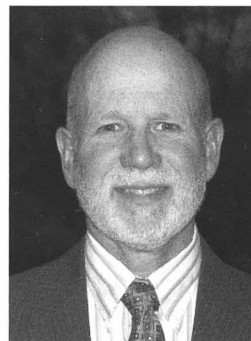
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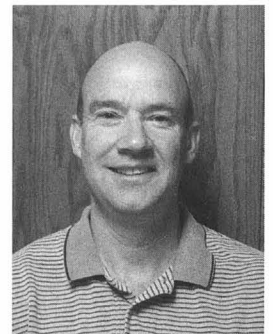
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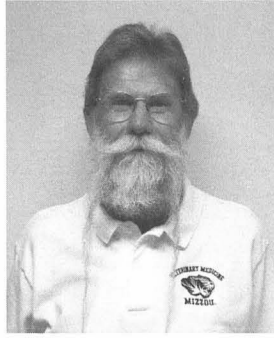
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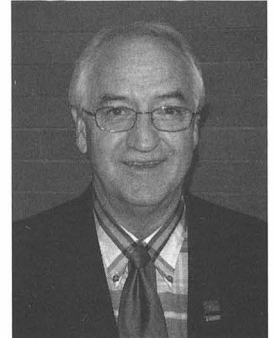
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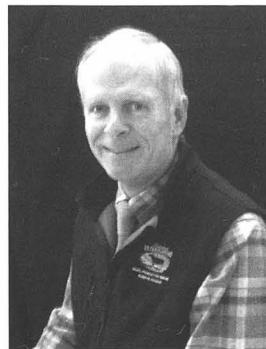
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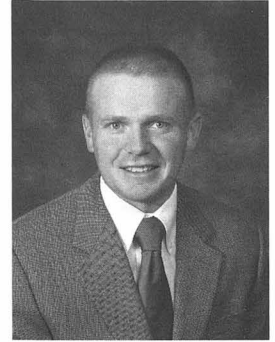
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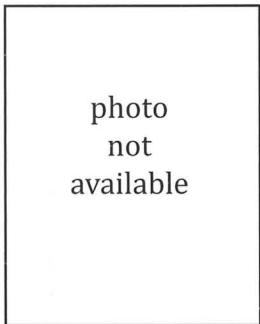
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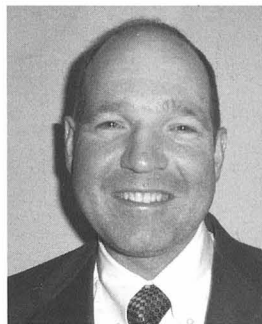
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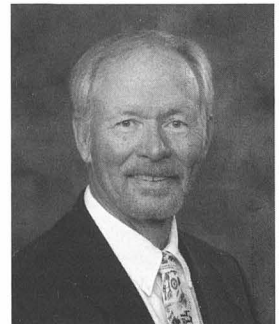
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INDICATIONS FOR USE: For the reduction in the incidence of clinical mastitis in the first 30 days of lactation in periparturient dairy cows and periparturient replacement dairy heifers.

DOSAGE AND ADMINISTRATION: This is a two-dose regimen. The same dose is used regardless of cow/heifer body weight. Remove surface dirt from the injection site area before injecting. Inject the entire contents of the syringe subcutaneously. Do not reuse the syringe.

Administer the first dose (syringe) 7 days prior to the cow's or heifer's anticipated calving date. If necessary, the first dose may be administered within a range of 4 to 10 days prior to the anticipated calving date to accommodate management schedules. Administer the second dose (syringe) within 24 hours after calving.

Animals that calve either less than or more than 7 days after the first dose should receive the second dose within 24 hours after calving.

Prior to administration, Imrestor should be visually inspected for particulate matter and discoloration. Imrestor is a clear, colorless solution and may contain a few small, translucent or white particles. Imrestor should not be used if it is discolored or cloudy, or if other particulate matter is present.

Do not shake or tap the syringe prior to use.

WARNINGS:

RESIDUE WARNING: No withdrawal period or milk discard time is required when used according to the labeling.

HUMAN WARNINGS: Not for use in humans. Keep out of reach of children.

USER SAFETY WARNINGS: In case of accidental self-injection, wash the site of injection thoroughly with clean running water. Foreign proteins such as pegbovigrastim have the potential to cause anaphylactic-type reactions. If you experience swelling or redness at the site of exposure, or more severe reactions such as shortness of breath, seek medical attention immediately and take the package insert with you. Report the event to Elanco Animal Health at 1-800-428-4441. To obtain a Safety Data Sheet, contact Elanco Animal Health at 1-800-428-4441.

PRECAUTIONS: Do not use Imrestor to treat cows with clinical mastitis because effectiveness has not been demonstrated for this use.

ADVERSE REACTIONS: Some cases of hypersensitivity-type reactions have been observed in studies outside the United States within five minutes to two hours, occurring most often after the first administration of Imrestor. Clinical signs may include elevated respiratory rate, dyspnea, urticaria, sweating, dependent edema, swollen mucous membranes, and/or hypersalivation, and, rarely death. These reactions resolve within hours of onset with or without therapeutic intervention and have not been shown to reoccur with subsequent injections of Imrestor. Abomasal ulcerations/erosions were observed in the Margin of Safety studies. (See Target Animal Safety section).

To report a suspected adverse drug event, contact Elanco Animal Health at 1-800-428-4441. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

EFFECTIVENESS: The effectiveness of Imrestor for the reduction in the incidence of clinical mastitis was demonstrated in a multi-site natural infection field study conducted at four sites in the U.S. and one site in France. A total of 801 healthy periparturient commercial dairy heifers and cows were enrolled and treated with Imrestor or saline by subcutaneous injection in the neck when they were identified as being approximately 7 days before their anticipated calving date (Day -7), and again within 24 hours after calving (Day 0). Each quarter of each enrolled animal was evaluated at each milking from Days 3 to 30 to monitor the development of clinical mastitis. Animals developing clinical mastitis (using quarter health, milk quality, and California Mastitis Test [CMT] evaluations) through Day 30 were classified as treatment failures. Administration of Imrestor resulted in a statistically significant difference ($p = 0.025$) in the incidence of clinical mastitis (treatment failure rate) across all five sites with a difference in favor of the Imrestor-treated group (failure rate: 60/331 = 18.13%) compared to the saline-treated group (failure rate: 85/338 = 25.15%).

STORAGE INFORMATION: Store under refrigeration (2° to 8°C; 36° to 46°F). DO NOT FREEZE. Avoid prolonged exposure to sunlight. Excursions of up to 24 hours at room temperature (15° to 30°C; 59° to 86°F) are allowed after receipt.

DISPOSAL: Dispose of used syringes in a leak-resistant, puncture-resistant container in accordance with applicable Federal, state and local regulations.

HOW SUPPLIED: 10, 50 or 100 single-dose syringe packages with each syringe containing 15 mg of pegbovigrastim.

NADA 141-392. Approved by FDA.

Manufactured for Elanco Animal Health, a Division of Eli Lilly and Company, Indianapolis, IN 46285.

For technical assistance or to report suspected adverse drug events, contact Elanco Animal Health at 1-800-428-4441.

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