Growth Promotant Use When Raising Beef | fact sheet

Growth Promotant Use

- Currently there are more than 30 Food and Drug Administration (FDA) approved growth promotant products marketed in the United States.[1]
- Growth promotants have been in use for over 50 years to raise more beef with fewer natural resources.
- Growth promotants have several different ways of administration:
    - Animals can eat the products through their feed.
    - The product is a small implant inserted under the skin in the animal's ear.
- Growth promotants are metabolized (used by the body) before the cattle go to the slaughterhouse.

Growth Promotants Recognized as Safe

- Before being allowed to enter the marketplace, growth promotants must go through a stringent multi-step, multi-year approval process that includes numerous rigorous studies, including human and animal health studies.[2]
- Growth promotants have been approved as safe for raising beef by many government agencies and groups world-wide including:
    - European Economic Community Scientific Working Group on Anabolic Agents
    - The International Codex Alimentarius Committee on Residues of Veterinary Drugs in Foods
    - European Agriculture Commission Scientific Conference on Growth Promotion In Meat Production
    - The Food and Agriculture Organization (FAO) and World Health Organization (WHO) Joint Expert Committee on Food Additives (JECFA).

Benefits of Growth Promotant Use

- Growth promotant use in cattle has allowed the beef community to raise more beef with fewer natural resources, without compromising the needs of future generations.
- The use of growth promotants improves cattle growth rates; doubling our beef production from 13.2 billion pounds to 27 billion pounds while decreasing the amount of land used for growing corn and roughage to feed cattle by 16 percent.[3]
- Growth promotant use has made today's beef leaner.
    - Cattle that have been given growth promotants have decreased their carcass fat from 35 percent to 27 percent.[3]

Growth Promotant Oversight

- Once approved by the FDA the company that manufactures the growth promotant must submit an annual Drug Experience Report to the FDA.[4] It consists of:
    - Sales figures
    - New research
    - Review of relevant safety date
    - Complaints received (producer and consumer)
- The Federal Meat Inspection Act mandates that the Food and Safety Inspection Service (FSIS) test for residues of growth promoting products at harvest that exceed FDA-established safe levels.[5]
    - Testing has been conducted since 1967.

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FDA Growth Promotant Approval

Ensuring Human Food Safety

A NADA sponsor (usually the manufacturing company applicant) must conduct tests to prove that food derived from treated animals is safe for human consumption. Required studies include research in the areas of metabolism, toxicity, residue and stability. FDA determines the specific testing requirements for evaluating the safety of each product.

The Delaney Clause, a 1958 amendment to the Federal Food, Drug and Cosmetic Act, prevents FDA from approving products that result in cancer-causing residues of chemicals in food. Therefore, growth promotants containing compounds with any potential for carcinogenicity—even if only in extreme circumstances—are subject to additional, stringent safety testing requirements before they can be approved for use in food animal production. (http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm123817.htm)

Setting Safe Levels

A NADA for growth promotants is not approved for use in food-producing animals until FDA evaluates the data and determines that the use of the drug will not result in unsafe residues in edible tissues. FDA establishes these safe residue levels using an Allowable Incremental Increase (AII) or Acceptable Daily Intake (ADI) approach, depending on product composition.

Allowable Incremental Increase

FDA scientists have determined it is safe to consume beef from cattle treated with growth promotants. They govern their use with the AII approach,which is the maximum increase in the natural hormone levels in beef allowed as a result of administering a growth promotant to cattle. By law, the AII for these products cannot exceed 1 percent of the total produced naturally by the human body. Additionally, the 1 percent must be calculated using the segment of the population that naturally produces the least amount of the specific hormone.

Acceptable Daily Intake

An ADI is the dose determined through extensive research to be safe to consume every day for a lifetime. FDA first establishes the "No Observable Effect Level" (NOEL), or the maximum level of the growth promoting compound that can be fed to the most sensitive laboratory animals with no adverse effects. The NOEL is then divided by a safety factor of at least 100 to determine the ADI. Thus, the ADI for humans is many times less than the amount that produces an effect in laboratory animals, creating a significant safety cushion. ADIs are expressed as dose/pound or kilogram of a person's body weight.

Environmental Safety

The National Environmental Policy Act of 1969 requires FDA to assess the environmental impacts of its actions. Therefore, all NADAs must include a claim for categorical exclusion or an environmental assessment (EA). As part of its EA, a manufacturer must measure and prove that the proposed product and its metabolized byproducts do not harm the environment in any way. CVM evaluates the assessment data and must issue a Finding of No Significant Impact (or FONSI) before the product can be approved. (http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/default.htm)

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1 *Food and Drug Administration: Adverse Drug Experience (ADE) Reports, http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055369.htm*

2 *USDA U.S. National Drug Residue Program: Red Book, http://www.fsis.usda.gov/PDF/2010_Red_Book.pdf*

3 *Food and Drug Administration Green Book On-line, http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042847*

4 *Food and Drug Administration New Animal Drug Application, http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/NewAnimalDrugApplications/default.htm*

5 *Thomas Elam, PhD, and Rodney Preston, PhD, Fifty Years of Pharmaceutical Technology and its Impact on the Beef We Provide to Consumers —http://www.sustainablebeef.org/_assets/SBRC-Fifty-Years-Technology-Impact.pdf*

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