# Government Approval of Growth Promotants | FACT SHEET

## Overview

Growth promotants are required to go through a comprehensive, multi-step scientific review by the Food and Drug Administration (FDA) to ensure animal health and human food safety. Approved products are regularly evaluated and must be continually proven safe to remain on the market.

## New Animal Drug Application Requirements

All growth promoting products are scrutinized under the New Animal Drug Application (NADA) process before approval, as mandated by the Federal Food, Drug and Cosmetic Act passed in 1938. The NADA process is a stringent, science-based regulatory review overseen by veterinarians, animal scientists and biologists who work in FDA's Office of New Animal Drug Evaluation within the Center for Veterinary Medicine (CVM).

Approval of a single growth promotant on average requires 75 studies to demonstrate human food safety, target animal safety and efficacy, environmental safety and user safety, in addition to a number of other requirements set by FDA (http://www.fda.gov/cvm/nadaappr.htm).

### 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.

### 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 naturally occurring growth hormones like estrogen, progesterone and testosterone. 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/cvm/ea.htm).







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## Ongoing Review of Product Safety

Once a growth promotant is approved, the sponsor must annually submit a Drug Experience Report to FDA that consists of sales figures, new research, a review of relevant safety data for the drug and any complaints received, including those from producer users as well as consumers. FDA's drug experience staff reviews the information and determines if any action is required, such as revised labeling, post-marketing research requirements or withdrawal from the market.

FDA has a staff of employees in each regulatory district of the United States who routinely inspect facilities where growth promotants are used and treated animals are processed. This inspection information also is analyzed by FDA to determine whether products should remain on the market.

Under the Federal Meat Inspection Act, the Food Safety and Inspection Service (FSIS) tests for residues of growth promoting products at harvest that exceed FDA-established safe levels. FSIS has conducted this testing since 1967. In 2005, the most current year data, FSIS reported zero residue violations for growth promotants in cattle (http://www.fsis.usda.gov/science/2005_Red_Book/index.asp).







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