



Current Good Manufacturing Practices



CGMPs for Medicated Feed
FSMA rule
VFD

OFFICE OF THE TEXAS STATE CHEMIST
Texas Feed and Fertilizer Control Service • Agriculture Analytical Service

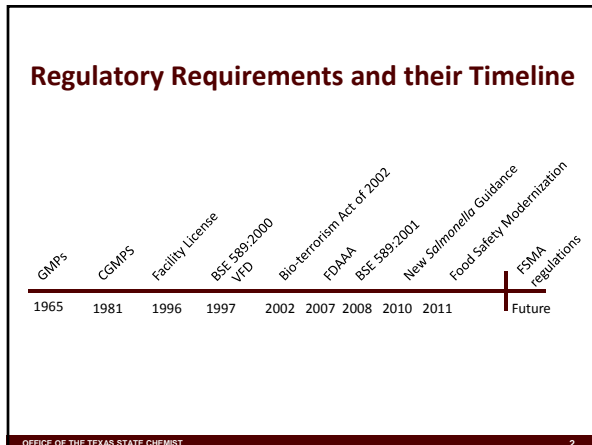


FDA CGMP Regulatory Framework

| | Category I Drugs | Category II Drugs |
|---|--|---|
| Use of Type B or Type C Medicated Feed | License and registration requirements, and full cGMPs apply if manufacturing medicated liquid feeds or medicated free-choice feed with a proprietary formula and/or specifications; otherwise No license No establishment registration No mandatory FDA inspections Relaxed cGMPs No required drug assays | License and registration requirements, and full cGMPs apply if manufacturing medicated liquid feeds or medicated free-choice feed; otherwise No license No establishment registration No mandatory FDA inspections Relaxed cGMPs No required drug assays |

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Source: Dave Fairfield, Feed Additive Compendium 2015 4



- ## Current Good Manufacturing Practices cGMPs cont.
- 225.1 Housekeeping requirements
 - 225.10 Personnel training
 - 225.20 Buildings
 - 225.30 Equipment
 - 225.42 Components (Inventory control)
 - 225.58 Laboratory controls
 - 225.65 Equipment cleanout
 - 225.80 Labeling
 - 225.102 Master record file and production records
 - 225.110 Distribution records
 - 225.115 Complaint files
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FDA CGMP Regulatory Framework

| | Category I Drugs | Category II Drugs |
|--|---|--|
| Manufacture of Type A Medicated Article | Premixes containing drugs at level greater than permitted in Type B feed | Premixes containing drugs at level greater than permitted in Type B feed |
| Use of Type A Medicated Article | No license No establishment registration No mandatory FDA inspections Relaxed cGMPs No required drug assays | License required Establishment registration Subject to routine FDA inspections Full cGMPs Drug assays required |

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Source: Dave Fairfield, Feed Additive Compendium 2015 3

- ## Current Good Manufacturing Practices cGMPs cont.
- Subpart F –
- 225.120 Buildings and grounds
 - 225.130 Equipment
 - 225.135 Work and storage areas
 - 225.142 Components
 - 225.158 Laboratory assays
 - 225.165 Equipment cleanout procedures,
 - 225.180 Labeling
 - 225.202 Formula, production and distribution records
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Results of Good Manufacturing Practices cGMPs

- Prior to 1978, the violation rate for sulfa drug residues were 13% in pork.
- Between 1980 to 1987, the violation rate dropped to 5%.
- Recently, the violation rate was less than 1%.

FSMA CGMPs

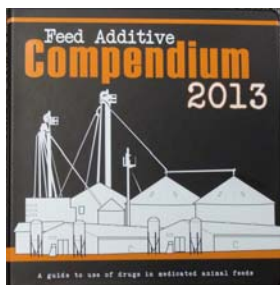
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.
Federal Register/Vol. 79, No. 188/Monday, September 29, 2014

In that 2013 proposed rule, we proposed to add CGMP requirements for animal food and to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk based preventive controls for food for animals.

Drug information Resources

Code of Federal Regulations

- Title 21 CFR Part 558



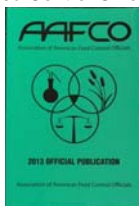
FSMA CGPMs cont.

Subpart B—Current Good Manufacturing Practice

- § 507.14 Personnel.
- § 507.17 Plant and grounds
- § 507.19 Sanitation
- § 507.20 Water supply and plumbing
- § 507.22 Equipment and utensils
- § 507.25 Plant operations
- § 507.27 Holding and distribution
- § 507.28 Holding and distribution of human food by-products for use as animal food.

Other Information Resources about CGMPs

- Association of American Feed Control Officials
- Feed Additive Compendium
- Animal Drug Suppliers
- Cooperative Extension
 - <http://www.grains.k-state.edu/extension/feed-manufacturing/publications.html>



Guidance for Industry #213

New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>



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