Introduction to Current Good Manufacturing Practices (cGMPs)

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Current Good Manufacturing Practices cGMPs

- Authority for the cGMP regulations is found in the Federal Food, Drug, and Cosmetic Act of 1938, commonly referred to as the (FD & C Act).
- Congress empowered the U.S. Food and Drug Administration or (FDA) to enforce the FD & C Act and other associated Acts.
- FDA enforces the regulations contained in Title 21 of the Code of Federal Regulations or (21 CFR).

Current Good Manufacturing Practices cGMPs cont.

- 21 CFR apply to food, drugs, and medical device products, including medicated feeds and animal drugs.
- The FD & C Act defines "Food" as (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.
- Medicated feeds include all feeds (supplements, concentrates, premixes, and complete feeds) that contain a drug and are intended as a substantial source of nutrients in the diet of the animal.

Current Good Manufacturing Practices cGMPs cont.

- The word "current" refers to the present good manufacturing practices regulations, not the past or future regulations.
- When conditions for production are less than those currently accepted and generally practiced by industry, the final product may be deemed to be adulterated from a regulatory perspective.
- cGMP standards refer to conditions under which the product is produced, not the condition of the final product.
- Products may be deemed to be adulterated if they are not produced in conformance with cGMP standards.

Current Good Manufacturing Practices cGMPs cont.

- The process for the development, finalization, and revision of cGMPs may require months of discussion between industry and FDA.
- cGMPs provide a preventative type approach to the control of the manufacture of medicated feeds.
- Flexibility in cGMP regulations provides for achieving specific outlined objectives and allows for the ability to stay current with change.
- Compliance with cGMPs should ensure the safety, effectiveness and quality of the medicated feeds produced.

Current Good Manufacturing Practices cGMPs cont.

cGMPs often are a result of common good business practices and include:

- Housekeeping requirements
- Personnel training
- Inventory control (drugs/medicated feeds)
- Documented history of production
- Equipment cleaning and maintenance
- Labeling
- Trace-back/recall procedures

Current Good Manufacturing Practices cGMPs cont.

- All manufacturers of medicated feeds must comply with cGMP regulations. This includes commercial feed mills, integrated operations, feedlots, and on-farm mixer-feeders.
- The GMP revision in 1981, referred to as the "Second Generation" program, created two sets of regulations. One for FDA licensed medicated feed establishments and one for non-licensed establishments.

Current Good Manufacturing Practices cGMPs cont.

- Medicated feed producers using Category II, Type A drug sources must register with FDA, obtain a license, and are subject to the more stringent cGMP regulations for licensed medicated feed establishments.
- Medicated feed producers using only Category I drugs and/or Category II, Type B drug sources, are not required to register with FDA or obtain a license. They are subject to the less stringent cGMP regulations for non-licensed establishments.

Current Good Manufacturing Practices cGMPs cont.

- Medicated feed – Any manufactured or mixed feed that contains drug ingredients intended to promote growth or feed efficiency or to cure, mitigate, prevent, or treat diseases of animals other than man.
- Category I drug – Drugs that require no withdrawal period at their lowest use level for all approved species.
- Category II drug – Drugs that require a withdrawal period at the lowest use level for at least one of the approved for use species.

Current Good Manufacturing Practices cGMPs cont.

- Type A medicated feed article – The most concentrated form of a medicated feed additive. It usually consists of a drug source and a carrier ingredient. It can be used in the manufacturing of another Type A medicated feed article or a Type B or Type C medicated feed.
- Type B medicated feed – A medicated feed containing an animal drug and a substantial amount of nutrients including vitamins, minerals, and other nutritional ingredients. Nutritional ingredients must make up at least 25% of the feed by weight. It can be diluted to manufacture other Type B or Type C medicated feed.

Current Good Manufacturing Practices cGMPs cont.

- Type C medicated feed – A medicated feed that is intended to be a complete feed. It can be fed as the sole ration, top-dressed onto another feed, or fed free-choice. It is manufactured by diluting a Type A medicated feed article or a Type B or Type C medicated feed.

Current Good Manufacturing Practices cGMPs cont.

- Sections 225.1 through 225.115 are the more stringent cGMPs and are applicable to FDA licensed medicated feed establishments.
- Sections 225.120 through 225.202 are the less stringent cGMPs and are applicable to non-licensed establishments.
- FDA licensed medicated feed establishments are subject to biennial compliance inspections by FDA or commissioned FDA agents (State Officials).
- Non-licensed establishments are not subject to routine, scheduled FDA inspections, but may be inspected "for cause" by FDA or commissioned FDA agents (State Officials).

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%.

Facility Licensing

Prior to 1996, feed manufacturers were required to submit an application (FDA 1900) for each Category II Type A medicated feed article used in the feed mill. Regulations, passed in 1996, now requires only a single application for the entire mill (Form FDA 3448).

"A licensed manufacturing site can make any approved medicated feed without having to submit additional paper work". (Graber 2000).

Veterinary Feed Directive

Historically, all drugs for use in medicated feed were made available on an over-the-counter (OTC) basis. In 1997, the Veterinary Feed Directive (VFD) category was created by Congress.

VFD drugs are available in Type A medicated feed articles, also as Type B and Type C medicated feeds. The FDA Center of Veterinary Medicine (CVM) determines whether a product is approved as a VFD or as an OTC.

Veterinary Feed Directive cont.

CVM policy is that all new antimicrobials for therapeutic use in feed will be approved as VFD drugs. VFD-medicated articles require that a veterinarian, under a valid vet-client relationship, examine and diagnose animal conditions and determine that the use of a VFD medicated feed is necessary.

Currently, there are only two approved VFD drugs.

- Tilmicosin Phosphate (Pulmotil) for use in swine.
- Florfenicol (Aquaflor) for use in swine and catfish.

Summary

- cGMPs are the regulatory standard for companies that manufacture medicated feed articles or medicated feeds.
- cGMPs also represent good business practices.
- The level of drug concentration and withdrawal period determine the degree of regulatory oversight.
- New medications may require a VFD prescription by a veterinarian.

End

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