Approved March 26, 1987
Date

MINUTES OF THE Senate COMMITTEE ON Agriculture.

The meeting was called to order by Senator Allen at
Chairperson

10:09 a.m./~~p.m.~~ on March 24, 1987 in room 423-S of the Capitol.

All members were present ~~except:~~ xxx

Committee staff present: Raney Gilliland, Legislative Research Department
Jill Wolters, Revisor of Statutes Department

Conferees appearing before the committee: Eldon Fastrup, Director, Division of Marketing
State Board of Agriculture
Larry Woodson, Director, Division of Inspections,
State Board of Agriculture
Glen Searcy, Control Supervisor, Division of
Inspections, State Board of
Agriculture

Senator Allen called the Committee to order; called attention to HB 2517; called on Eldon Fastrup to testify.

Mr. Fastrup expressed support for HB 2517 and explained the bill, if passed, would allow the State Board of Agriculture to set up two accounts for funds handled by the Marketing Division. These funds pertain to cost of and monies received from their registered trade mark, with costs of seminars, with costs of trade shows, and with promotional materials. The accounts requested would allow for a more systematic method of handling the funds.

The Chairman thanked Mr. Fastrup and declared the hearing completed for HB 2517 and called attention to HB 2519; he called on Larry Woodson to testify.

Mr. Woodson gave copies of his testimony to the Committee (attachment 1) and expressed support for HB 2519. Mr. Woodson introduced Glen Searcy to comment.

Mr. Searcy expressed support for HB 2519; he stated need to have what they are already doing incorporated into law. The provisions are designed to prevent contamination of feeds being prepared for livestock.

The Chairman thanked Mr. Searcy and declared the hearing closed for HB 2519; he then turned the Committees' attention to HB 2076 for further discussion.

Committee comments centered around facts that there is not enough support to amend swine back into the bill, that an indepth study of the whole Corporate Farm Bill has support, that the House is drafting a Resolution to request an indepth study of the Corporate Farm Bill, that the Committee should report HB 2076 adversely, that this bill is small in scope when the total picture is large, that when action is taken on corporate confinement facilities the total picture should be addressed, the issue must be addressed so that if we have corporate farming that the small farmers have the same tax breaks, the same advantages and that the issue be studied as a totally statewide issue. Further comments included the desire to have corporate swine production in our state, that corporate cattle feedlots in Western Kansas have caused depletion of markets for the small cattle man of Eastern Kansas but have been a boom to Western Kansas, that there are advantages to some corporate operations for our state but that many do not understand or see any benefits, it was also stated the intent of the first corporate farm bill was to be able to control land ownership so as to prevent unfair land operations.

MINUTES OF THE Senate COMMITTEE ON Agriculture,

room 423-S, Statehouse, at 10:09 a.m./~~p.m.~~ on March 24, 1987

Senator Doyen made a motion that HB 2076 be reported adversely. Senator Norvell seconded the motion. During discussion the request was made to allow poultry and rabbits and with that maybe people of Kansas would see some corporate projects are good for the state. A request was made to keep HB 2076 alive.

Senator Gannon made a substitute motion to amend HB 2076 to include rabbits. Senator Karr seconded the motion. Motion carried. Senator Montgomery requested the record show that he voted no.

Senator Doyen remade a motion that HB 2076 be reported adversely. Senator Norvell seconded the motion. The motion failed. Senator Montgomery requested the record show that he voted yes.

After staff suggested, Senator Karr made a conceptional motion that the language of lines 160 and 236 be amended to be compatible. Senator Montgomery seconded the motion. Motion carried.

The Chairman announced further discussion of HB 2076 would be at a later Committee meeting; he then called for action on Committee minutes.

Senator Karr moved the Committee minutes for March 23 be approved. Senator Warren seconded the motion. Motion carried.

The Chairman adjourned the Committee at 10:54 a.m.

GUEST LIST

COMMITTEE: SENATE AGRICULTURE DATE: March 24, 1987

NAME (PLEASE PRINT)	ADDRESS	COMPANY/ORGANIZATION
Carl J. Patterson	Topeka	K.C. Times
Ellen R Fastrup	Topeka	KS Board of Agriculture
Gale Sweetser	✓	✓
Charlene Patton	✓	✓
MIKE BEAM	TOPEKA	KS. LUSTK. ASSN.
Ramona Jones	Topeka	Wichita Eagle-Beacon
Julie Andsager	Topeka	Ks Co-op Council
LARRY D. WOODSON	TOPEKA	KBOAg.
Glen H Searcy	Topeka	KBOAg
Scott C. Bangert	Topeka	KBO Ag
BILL R. FULLER	Manhattan	Kansas Farm Bureau
Chris Wilson	Hutchinson	KS Grain & Feed Ass'n

PRESENTATION TO THE

SENATE AGRICULTURE COMMITTEE

by

Larry D. Woodson
Division of Inspections

Good Morning. Mr. Chairman, Members of the Senate Agriculture Committee. My name is Larry Woodson, Director of the Division of Inspections, with the Kansas State Board of Agriculture. With me today are: Archie Hurst, Assistant Director and Glen Searcy, Control Supervisor; all of the Kansas State Board of Agriculture.

HB 2519 addresses the amendment of the Kansas Feeding Stuffs Law to include a provision regarding Good Manufacturing Practices or GMP's. It is the position of the Kansas State Board of Agriculture that the adoption of GMP's would help assure that good practices are being used to manufacture feeding stuffs in Kansas.

GMP's have been adopted in 22 states including Colorado, Oklahoma, Nebraska, Iowa, Minnesota and South Dakota to mention those in this area.

One reason that GMP's are now important is due to FDA's new program - Generation Two - which changed the guidelines that FDA followed. As a result of Generation Two, FDA only regulates those firms that utilize 1900 drugs - i.e. those used in higher concentrations or those that may be potentially more dangerous if not used properly.

Firms not utilizing 1900 drugs would be affected by GMP's and inspected by the State Board of Agriculture.

GMP's include proper procedures, equipment maintenance, correct labeling, adequate storage of medications, accurate measuring or weighing devices or equipment and other areas as stated on the attachment.

attachment 1
Senate agriculture
3-24-87

We believe that the adoption of GMP's will enable us to provide more efficient inspection by identifying and correcting problem areas rather than to rely upon random samples and laboratory analysis to detect violations.

The GMP's that are attached are a part of the uniform feed law which is published by the Association of American Feed Control Officials.

The adoption of the GMP's should not result in a significant fiscal impact upon industry nor upon the agency.

Tom Bishop, President of the Kansas Formula Feed Manufacturers has advised the Division that he is in support of this amendment.

Mr. Glen Searcy, Control Supervisor, or other staff members in attendance will attempt to answer your questions.

attachment 1

3-24-87

Text of the Food and Drug Administration's Good Manufacturing Practice Regulations

EDITOR'S NOTE: Below is the text of the Food & Drug Administration's Good Manufacturing Practices. These GMPs were published by FDA in the Nov. 30, 1976, Federal Register and were revised in the March 3, 1986, Federal Register.

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

Part 210 is amended by revising the part heading as set out above.

In §210.3 by revising paragraph (b)(13) and (14), to read as follows:

§210.3 Definitions.

(b)***

(13) The term "medicated feed" means any Type B or Type C medicated feed as defined in §558.3 of this chapter. The feed contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated feeds is subject to the requirements of Part 225 of this chapter.

(14) The term "medicated premix" means a Type A medicated article as defined in §558.3 of this chapter. The article contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated premixes is subject to the requirements of Part 226 of this chapter.

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

Subpart A—General Provisions

Subpart B—Construction and Maintenance of Facilities and Equipment

Subpart C—Product Quality Control

Subpart D—Packaging and Labeling

Subpart E—Records and Reports

Subpart F—Facilities and Equipment

Subpart G—Product Quality Assurance

Subpart H—Labeling

Subpart I—Records

Subpart A—General Provisions

§225.1 Current good manufacturing practice.

(a) Section 501 (a) (2) (B) of the Federal Food, Drug, and Cosmetic Act provides that a drug (including a drug contained in a medicated feed) shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirement of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(b)(1) The provisions of this part set forth the criteria for determining whether the manufacture of a medicated feed is in compliance with current good manufacturing practice. These regulations shall apply to all types of facilities and equipment used in the production of medicated feeds, and they shall also govern those instances in which failure to adhere to the regulations has caused nonmedicated feeds that are manufactured, processed, packed, or held to be adulterated. In such cases, the medicated feed shall be deemed to be adulterated within the meaning of section 501(a)(2)(B) of the act, and the nonmedicated feed shall be deemed to be adulterated within the meaning of section 402(a)(2)(D) of the act.

(2) The regulations in §§225.10 through 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed application is required. The regulations in §§225.120 through 225.202 apply to facilities manufacturing solely medicated feeds for which approved medicated feed applications are not required.

§ 225.10 Personnel.

(a) Qualified personnel and adequate personnel training and supervision are essential for the proper formulation, manufacture, and control of medicated feeds. Training and experience lead to proper use of equipment, maintenance of accurate records and detection and prevention of possible deviations from current good manufacturing practices.

(b) (1) All employees involved in the manufacture of medicated feeds shall have an understanding of the manufacturing or control operation(s) which they perform, including the location and proper use of equipment.

(2) The manufacturer shall provide an on-going program of evaluation and supervision of employees in the manufacture of medicated feeds.

Subpart B—Construction and Maintenance of Facilities and Equipment

§ 225.20 Buildings.

(a) The location, design, construction and physical size of the buildings and other

production facilities are factors important to the manufacture of medicated feed. The features of facilities necessary for the proper manufacture of medicated feed include provision for ease of access to structures and equipment in need of routine maintenance; ease of cleaning of equipment and work areas; facilities to promote personnel hygiene; structural conditions for control and prevention of vermin and pest infestation; adequate space for the orderly receipt and storage of drugs and feed ingredients and the controlled flow of these materials through the processing and manufacturing operations, and the equipment for the accurate packaging and delivery of a medicated feed of specified labeling and composition.

(b) The construction and maintenance of buildings in which medicated feeds are manufactured. processed, packaged, labeled or held shall conform to the following:

(1) The building grounds shall be adequately drained and routinely maintained so that they are reasonably free from litter, waste, refuse, uncut weeds or grass, standing water and improperly stored equipment.

(2) The building(s) shall be maintained in a reasonably clean and orderly manner.

(3) The building(s) shall be of suitable construction to minimize access by rodents, birds, insects and other pests.

(4) The buildings shall provide adequate space and lighting for the proper performance of the following medicated feed manufacturing operations:

(i) the receipt, control and storage of components.

(ii) component processing.

(iii) Medicated feed manufacturing.

(iv) Packaging and labeling.

(v) Storage of containers, packaging materials, labeling and finished products.

(vi) Routine maintenance of equipment.

§ 225.30 Equipment

(a) Equipment which is designed to perform its intended function and is properly installed and used is essential to the manufacture of medicated feeds. Such equipment permits production of feeds of uniform quality, facilitates cleaning and minimizes spillage of drug components and finished product.

(b) (1) All equipment shall possess the capability to produce a medicated feed of intended potency, safety and purity.

(2) All equipment shall be maintained in a reasonably clean and orderly manner.

(3) All equipment, including scales and liquid metering devices, shall be of suitable size, design, construction, precision and accuracy for its intended purpose.

(4) All scales and metering devices shall be tested for accuracy upon installation and at least once a year thereafter, or more frequently as may be necessary to insure their accuracy.

(5) All equipment shall be so constructed and maintained as to prevent lubricants and coolants from becoming unsafe additives in feed components or medicated feed.

(6) All equipment shall be designed, constructed, installed, and maintained so as to facilitate inspection and use of clean-out procedure(s).

§ 225.35 Use of work areas, equipment, and storage areas for other manufacturing and storage purpose.

(a) Many manufacturers of medicated feeds are also involved in the manufacture, storage or handling of products which are not intended for animal feed use, such as fertilizers, herbicides, insecticides, fungicides, rodenticides and other pesticides. Manufacturing, storage or handling of non-feed and feed products in the same facilities may cause adulteration of feed products with toxic or otherwise unapproved feed additives.

(b) Work areas and equipment used for the manufacture or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture of fertilizers, herbicides, insecticides, fungicides, rodenticides and other pesticides unless such articles are approved drugs or approved food additives intended for use in the manufacture of medicated feed.

Subpart C—Product Quality Control

§ 225.42 Components.

(a) A medicated feed, in addition to providing nutrients, is a vehicle for the administration of a drug, or drugs, to animals. To ensure proper safety and effectiveness, such medicated feeds must contain the labeled amounts of drugs. It is necessary that adequate procedures be established for the receipt, storage and inventory control for all such drugs to aid in assuring their identity, strength, quality and purity when incorporated into products.

(b) The receipt, storage and inventory of drugs, including undiluted drug components, medicated premixes and semiprocessed (i.e., intermediate premixes, in-plant premixes and concentrates) intermediate mixes containing drugs, which are used in the manufacture and processing of medicated feeds, shall conform to the following:

(1) Incoming shipments of drugs shall be visually examined for identity and damage. Drugs which have been subjected to conditions which may have adversely affected their identity, strength, quality or purity shall not be accepted for use.

(2) Packaged drugs in the storage areas shall be stored in their original closed containers.

(3) Bulk drugs shall be identified and stored in a manner such that their identity, strength, quality and purity will be maintained.

(4) Drugs in the mixing areas shall be properly identified, stored, handled and controlled to maintain their integrity and identity. Sufficient space shall be provided for the location of each drug.

(5) A receipt record shall be prepared and maintained for each lot of drug received. The receipt record shall accurately indicate the identity and quantity of the drug, the name of the supplier, the supplier's lot number or an identifying number assigned by the feed manufacturer upon receipt which relates to the particular shipment, the date of receipt, the condition of the drug when received and the return of any damaged drugs.

(6) A daily inventory record for each drug used shall be maintained and shall list by manufacturer's lot number or the feed manufacturer's shipment identification number at least the following information:

(i) The quantity of drugs on hand at the beginning and end of the work day (the beginning amount being the same as the previous day's closing inventory if this amount has been established to be correct); the quantity shall be determined by weighing, counting or measuring, as appropriate.

(ii) The amount of each drug used, sold or otherwise disposed of.

(iii) The batches or production runs of medicated feed in which each drug was used.

(iv) When the drug is used in the preparation of a semiprocessed intermediate mix intended for use in the manufacture of medicated feed, any additional information which may be required for the purpose of paragraph (b) (7) of this section.

(v) Action taken to reconcile any discrepancies in the daily inventory record.

(7) Drug inventory shall be maintained of each lot or shipment of drug by means of a daily comparison of the actual amount of drug used with the theoretical drug usage in terms of the semiprocessed, intermediate and finished medicated feeds manufactured. Any significant discrepancy shall be investigated and corrective action taken. The medicated feed(s) remaining on the premises which are affected by this discrepancy shall be detained until the discrepancy is reconciled.

(8) All records required by this section shall be maintained on the premises for at least one year after complete use of a drug component of a specific lot number or feed manufacturer's shipment identification number.

§ 225.58 Laboratory controls.

(a) The periodic assay of medicated feeds for drug components provides a measure of performance of the manufacturing process in manufacturing a uniform product of intended potency.

(b) The following assay requirements shall apply to medicated feeds:

(1) For feeds requiring approved Medicated Feed Applications (Form FDA 1900)

for their manufacture and marketing: At least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by approved official methods, at periodic intervals during the calendar year, unless otherwise specified in this chapter. At least one of these assays shall be performed on the first batch using the drug. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested.

(2) (Reserved)

(c) The originals or copies of all results of assays, including those from State feed control officials and any other governmental agency, shall be maintained on the premises for a period of not less than 1 year after distribution of the medicated feed. The results of assays performed by State feed control officials may be considered toward fulfillment of the periodic assay requirements of this section.

(d) Where the results of assays indicate that the medicated feed is not in accord with label specifications or is not within permissible assay limits as specified in this chapter, investigation and corrective action shall be implemented and an original or copy of the record of such action maintained on the premises.

(e) Corrective action shall include provisions for discontinuing distribution where the medicated feed fails to meet the labeled drug potency. Distribution of subsequent production of the particular feed shall not begin until it has been determined that proper control procedures have been established.

§ 225.65 Equipment cleanout procedures.

(a) Adequate cleanout procedures for all equipment used in the manufacture and distribution of medicated feeds are essential to maintain proper drug potency and avoid unsafe contamination of feeds with drugs. Such procedures may consist of cleaning by physical means; e.g., vacuuming, sweeping, washing. Alternatively, flushing or sequencing or other equally effective techniques may be used whereby the equipment is cleaned either through use of a feed containing the same drug(s) or through use of drug-free feedstuffs.

(b) All equipment, including that used for storage, processing, mixing, conveying and distribution that comes in contact with the active drug component feeds in process or finished medicated feed shall be subject to all reasonable and effective procedures to prevent unsafe contamination of manufactured feed. The steps used to prevent unsafe contamination of feeds shall include one or more of the following, or other equally effective procedures:

(1) Such procedures shall, where appropriate, consist of physical means (vacuuming, sweeping or washing), flushing, and/or sequential production of feeds.

(2) If flushing is utilized, the flush material shall be properly identified, stored and used in a manner to prevent unsafe contamination of other feeds.

(3) If sequential production of medicated feeds is utilized, it shall be on a predetermined basis designed to prevent unsafe contamination of feeds with residual drugs.

Subpart D—Packaging and Labeling

§ 225.80 Labeling

(a) Appropriate labeling identifies the medicated feed and provides the user with directions for use which, if adhered to, will assure that the article is safe and effective for its intended purposes.

(b) (2) Labels and labeling, including placards, shall be received, handled and stored in a manner that prevents labeling mixups and assures that correct labeling is employed for the medicated feed.

(b) (1) Labels and labeling, including placards, upon receipt from the printer shall be proofread against the Master Record File to verify their suitability and accuracy. The proofread label shall be dated, initialed by a responsible individual and kept for one year after all the labels from that batch have been used.

(3) In those instances where medicated feeds are distributed in bulk, complete labeling shall accompany the shipment and be supplied to the consignee at the time of delivery. Such labeling may consist of a placard or other labels attached to the invoice or delivery ticket or manufacturer's invoice that identifies the medicated feed and includes adequate information for the safe and effective use of the medicated feed.

(4) Label stock shall be reviewed periodically, and discontinued labels shall be discarded.

Subpart E—Records and Reports

§ 225.102 Master record file and production records.

(a) The Master Record File provides the complete procedure for manufacturing a specific product, setting forth the formulation, theoretical yield, manufacturing procedures, assay requirements(s) and labeling of batches or production runs. The production record(s) include(s) the complete history of a batch or production run. This record includes the amounts of drugs used, the amount of medicated feed manufactured and provides a check for the daily inventory record of drug components.

(b) The Master Record File and production records shall comply with the following provisions:

(1) A Master Record File shall be prepared, checked, dated and signed or initialed by a qualified person and shall be retained for not less than one year after production of the last batch or production run of medicated feed to which it pertains. The Master Record File or card shall include at least the following:

(i) The name of the medicated feed.

(ii) The name and weight percentage or measure of each drug or drug combination and each nondrug ingredient to be used in manufacturing a stated weight of the medicated feed.

(iii) A copy or description of the label or labeling that will accompany the medicated feed.

(iv) Manufacturing instructions or reference thereto that have been determined to yield a properly mixed medicated feed of the specified formula for each medicated feed produced on a batch or continuous operation basis, including mixing steps, mixing times and, in the case of medicated feeds produced by continuous production run, any additional manufacturing directions including, when indicated, the setting of equipment.

(v) Appropriate control directions or reference thereto, including the manner and frequency of collecting the required number of samples for specified laboratory assay.

(2) The original production record or copy thereof shall be prepared by qualified personnel for each batch or run of medicated feed produced and shall be retained on the premises for not less than one year. The production record shall include at least the following:

(i) Product identification, date of production and a written endorsement in the form of a signature or initials by a responsible individual.

(ii) The quantity and name of drug components used.

(iii) The theoretical quantity of medicated feed to be produced.

(iv) The actual quantity of medicated feed produced. In those instances where the finished feed is stored in bulk and actual yield cannot be accurately determined, the firm shall estimate the quantity produced and provide the basis for such estimate in the Master Record File.

(3) In the case of a custom formula feed made to the specifications of a customer, the master Record File and production records required by this section shall consist either of such records or of copies of the customer's purchase orders and the manufacturer's invoices bearing the information required by this section. When a custom order is received by telephone, the manufacturer shall prepare the required production records.

(4) Batch production records shall be checked by a responsible individual at the end of the working day in which the product was manufactured to determine whether all required production steps have been performed. If significant discrepancies are noted, an investigation shall be instituted immediately, and the production

record shall describe the corrective action taken.

(5) Each batch or production run of medicated feed shall be identified with its own individual batch or production run number, code, date or other suitable identification applied to the label, package, invoice or shipping document. This identification shall permit the tracing of the complete and accurate manufacturing history of the product by the manufacturer.

§ 225.110 Distribution records.

(a) Distribution records permit the manufacturer to relate complaints to specific batches and/or production runs of medicated feed. This information may be helpful in instituting a recall.

(b) Distribution records for each shipment of a medicated feed shall comply with the following provisions:

(1) Each distribution record shall include the date of shipment, the name and address of purchaser, the quantity shipped and the name of the medicated feed. A lot or control number, or date of manufacture or other suitable identification shall appear on the distribution record or the label issued with each shipment.

(2) The originals or copies of the distribution records shall be retained on the premises for not less than one year after the date of shipment of the medicated feed.

§ 225.115 Complaint files.

(a) Complaints and reports of experiences of product defects relative to the drug's efficacy or safety may provide an indicator as to whether or not medicated feeds h ave been manufactured in conformity with current good manufacturing practices. These complaints and experiences may reveal the existence of manufacturing problems not otherwise detected through the normal quality control procedures. Timely and appropriate follow-up action can serve to correct a problem and minimize future problems.

(b) The medicated feed manufacturer shall maintain on the premises a file which contains the following information:

(1) The original or copy of a record of each oral and written complaint received relating to the safety and effectiveness of the product produced. The record shall include the date of the complaint, the complainant's name and address, name and lot or control number or date of manufacture of the medicated feed involved, and the specific details of the complaint. This record shall also include all correspondence from the complainant and/or memoranda of conversations with the complainant and a description of all investigations made by the manufacturer and of the method of disposition of the complaint.

(2) For medicated feeds requiring an approved Medicated Feed Application (Form FDA 1900), records and reports of clinical and other experience with the drug shall be maintained and reported, appropriately identified with the number(s) of the Form FD-1800 to which they relate, to the Bureau of Veterinary Medicine, 5600 Fishers Lane, Rockville, Md. 20857, in duplicate, pursuant to § 510.301 of this chapter.

Subpart F—Facilities and Equipment

§225.120 Buildings and grounds.

Buildings used for production of medicated feed shall provide adequate space for equipment, processing, and orderly receipt and storage of medicated feed. Areas shall include access for routine maintenance and cleaning of equipment. Buildings and grounds shall be constructed and maintained in a manner to minimize vermin and pest infestation.

§225.130 Equipment.

Equipment shall be capable of producing a medicated feed of intended potency and purity, and shall be maintained in a reasonably clean and orderly manner. Scales and liquid metering devices shall be accurate and of suitable size, design, construction, precision, and accuracy for their intended purposes. All equipment shall be designed, constructed, installed, and maintained so as to facilitate inspection and use of cleanout procedure(s).

§225.135 Work and storage areas.

Work areas and equipment used for the production or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture and storage of fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides unless such articles are approved for use in the manufacture of animal feed.

Subpart G—Product Quality Assurance

§ 225.142 Components.

Adequate procedures shall be established and maintained for the identification, storage, and inventory control (receipt and use) of all Type A medicated articles and Type B medicated feeds intended for use in the manufacture of medicated feeds to aid in assuring the identity, strength, quality, and purity of these drug sources. Packaged Type A medicated articles and Type B medicated feeds shall be stored in designated areas in their original closed containers. Bulk Type A medicated articles and bulk Type B medicated feeds shall be identified and stored in a manner such that their identity, strength, quality, and purity will be maintained. All Type A medicated articles and Type B medicated feeds shall be used in accordance with their labeled mixing directions.

§225.158 Laboratory assays.

Where the results of laboratory assays of drug components, including assays by State feed control officials, indicate that the medicated feed is not in accord with the permissible limits specified in this chapter, investigation and corrective action shall be implemented immediately by the firm and such records shall be maintained on the premises for a period of 1 year.

§225.165 Equipment cleanout procedures.

Adequate procedures shall be established and used for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and nonmedicated feeds.

Subpart H—Labeling

§225.180 Labeling.

Labels shall be received, handled, and stored in a manner that prevents label mixups and assures that the correct labels are used for the medicated feed. All deliveries of medicated feeds, whether bagged or in bulk, shall be adequately labeled to assure that the feed can be properly used.

Subpart I—Records

§225.202 Formula, production, and distribution records.

Records shall be maintained identifying the formulation, date of mixing, and if not for own use, date of shipment. The records shall be adequate to facilitate the recall of specific batches of medicated feed that have been distributed. Such records shall be retained on the premises for 1 year following the date of last distribution.

The 'new' current Good Manufacturing Practice regulations for medicated feeds

Dr. Robert A. Wilcox is professor and quality control specialist, formula feed extension, Department of Grain Science and Industry, Kansas State University, Manhattan, Kan. He received his Ph.D. degree in animal science and biochemistry-nutrition at South Dakota State University in 1960. He was director of nutrition for H.J. Heinz, GTA and Standard Chemical Mfg. before coming to Kansas State.

By Dr. Robert A. Wilcox

The "Second Generation" medicated feed regulations of the Food & Drug Administration (FDA) were published in the March 3, 1986, *Federal Register* and are effective beginning May 2, 1986, for those Category I drugs formerly requiring an approved Form FDA 1800 and beginning March 3, 1987, for those Category II drugs that formerly did not require the approved FDA 1800.

As was true for the former regulations, these Current Good Manufacturing Practice Regulations (CGMP) define the quality control procedures that FDA deems necessary for the manufacture of medicated feed. Feed manufacturers have used their own versions of quality control (or quality assurance) to maintain the quality of their feeds, so these revised regulations do not really impose that much of a burden on the industry.

Some feed manufacturers are still lax in keeping track of drug inventories and drug assays. Some still need improvement in the way they handle and weigh drug additions to the feeds. Some have equipment that does not properly blend the drugs into the medicated feed being produced. Some have equipment that "carries over" significant amounts of medicated feed into the following batch of feed. For these, complying with the CGMPs should help to bring them up to an acceptable level of quality control for the medicated feeds being produced. This is in the best interests of both the feed manufacturer and his customers.

All drugs are in either Category I or Category II. Category I drugs are those for which no withdrawal time is required at the lowest use level. Category II drugs are those that either (1) have withdrawal times at the lowest use level for one or more species or (2) are regulated because of a "no-residue" or "zero" tolerance basis.

All medicated feeds are classed as Types A, B or C. Type A medicated articles are the former medicated premixes (superconcentrates and fortifiers may fall into this category depending on the level of drugs in the final product) and require an approved Form 356 (new animal drug application) to be manufactured (with certain exceptions).

Type B medicated feeds are dilute drug premixes and include feed concentrates, supplements and other mixtures that have to be mixed with one or more ingredients before being fed to animals.

Type C medicated feeds are essentially complete feeds ready to be fed to animals as the only feed or as a top-dress or in a free-choice offering.

Type A Medicated Article(s) come under the same CGMPs that applied to the former medicated premixes (Part 226 of the regulations). These are more stringent than the CGMPs that apply to Types B and C (Part 225).

All manufacturers of medicated feeds can be held responsible for complying with the CGMPs. However, only those who are required to have drug approvals (Form FDA 1800s and FDA 1900s) will be required to be registered with the FDA and be subject to biennial inspections. Those manufacturers exempted from registering may still be inspected if a drug residue problem is traced to their products. They are subject to simplified CGMP regulations.

Feed manufacturers are exempt from registration if they use Category I, Type A Medicated Articles and Category II, Type B Medicated Feeds as the source of drugs for the production of Type B and Type C Medicated feeds. Not being registered means that the firm would not be subject to biennial inspections, would not need approved 1800s and/or 1900s and would not have to pass a preapproval inspection. These firms could be inspected in conjunction with a violative residue problem and are expected to be in compliance with parts 225.120 through 225.202 of the regulations.

Firms that manufacture Type B or C feeds using a Type A feed that has a Category II drug(s) in it will be required to have passed previous FDA inspections or a preapproval inspection, to have currently approved 1800s (which will continue to be valid after March 3, 1987) or to have newly approved FDA 1900s for the animal drugs being incorporated into medicated feeds, to register with FDA (if not currently registered), and be in compliance with the CGMP regulations (Parts 225.10 through 225.115).

Type B Medicated feeds are determined by the level of drug in the final product. The maximum levels are presented in tables of the CGMP that accompany this article. Any medicated feed that has drug levels above these indicated levels will be classed as a Type A Medicated Article. The maximum level of a Category I drug in a Type B feed is 200 times the highest continuous use level. The maximum level of a Category II drug in a Type B feed is 100 times the highest continuous use level.

Type C Medicated feeds are those with drug levels approved for direct feeding to animals (as presented in this Compendium). As mentioned above, they can be fed as the sole feed, as top dressing on other feedstuffs or as a part of a free-choice feeding system.

The following points are the gist of the CGMP regulations (but not necessarily comprehensive). These may help in understanding the actual CGMP that follow this article.

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

Subpart A—General provisions

225.1—Current Good Manufacturing Practice

- Your medicated feeds are adulterated if you don't comply.
- Your non-medicated feeds are adulterated if drug carryover is found.

225.10—Personnel

- Train your employees in the manufacture of medicated feeds.
- Provide on-the-job training and refresher courses.

Subpart B—Construction and maintenance of facilities and equipment

225.20—Buildings

- Your building should allow you to produce medicated feed that conforms to your labeling and with your production formula.
- The surrounding area should drain water.
- The surrounding area should be reasonably free of litter, waste, refuse, uncut weeds, uncut grass, standing water and improperly stored equipment.
- Have control of rodents, birds, insects and other pests.
- Have enough room and lights to do a good job of producing feed.

225.30—Equipment

- Your equipment ought to do what it is supposed to do without drug carryover problems or drug assay problems.
- Keep it reasonably clean and orderly.
- Test scales and meters at least once a year.
- Keep lubricants, coolants and other non-feed materials out of feeds.

225.35—Use of work areas, equipment and storage areas for other manufacturing and storage purposes.

- Do not use feed equipment to handle, mix or store fertilizers, herbicides, insecticides, fungicides, rat or mouse poisons or other pesticides (exception: those approved and intended for use in a medicated feed).

Subpart C—Product quality control

225.42—Components

- Look for damage to incoming drug packages (refuse to accept significantly damaged containers).
- Are they labeled correctly (agree with invoice or order)?
- Keep packaged drugs in original containers while awaiting use.
- In mixing area, keep ingredients (especially drugs) identified.
- Drug receipt record—name, amount, supplier, either lot number or other identifier, date, condition, any returns and whatever else you want to put down.
- Keep a daily drug inventory (take at end of work day) that can be checked against previous inventory after subtracting amount used during work day. Drug records are not required for medicated concentrates and supplements which do not need an approved Form 1900 for further mixing.

Note: In practice, daily inventoring of drugs applies to those drugs that were used during the work day. Drugs not used during the work day need not be re-weighed but you should indicate on the drug record "not used" for the particular date. A systematic procedure of checking weights of all drugs every day is recommended.

- Compare drug inventory with calculated usage—investigate promptly any discrepancy.
- Keep these records one year after complete use of a lot or shipment.

225.58—Laboratory Records

- Three assays a year on Form 1800 and Form 1900 feeds.
- Stop production and distribution if assays are out of tolerance.
- Keep copies of all assays, including state feed control assays, for one year after feed has been distributed.
- State feed control assays can substitute for the annual assays required.

225.65—Equipment Cleanout Procedures

- Do what it takes to prevent unsafe drug carryover.
- One way is to have a planned sequence of feeds to be made after the production of certain medicated feeds.

225.80—Labeling

- Don't get them mixed up (wrong label is a common violation).
- Proofread new or revised labels and catch those printed errors before they catch you.
- Throw out old labels—someone might use them.
- Proofread label should be dated, initialed by a responsible individual and filed for one year after labels have been used up.

Subpart E—Records and reports

225.102—Master Record File

- Has complete procedure for manufacturing a specific product. Includes formula and theoretical yield.
- Keep on file one year after last production—mark it so that it is recognized as an old formula in that last year.
- Original must be prepared, checked, dated and signed (initialed) by a qualified person.
- Needs feed name, drug component, label, manufacturing instructions and sampling schedule.

225.102—Production Records

- Prepared for each batch or run of medicated feed.
- Original and copies prepared and initialed or signed by qualified person.
- Identification of feed, date, drug amount, theoretical quantity produced and initialed by the person responsible for feed production—keep one year.
- Include actual quantity of feed produced (estimate o.k. for bulk).
- Customer formula record needs above information.
- Check batch production records at close of work day to catch production errors—if found, take corrective action.
- Each batch or production run needs identification so that you can trace the feed from production to customer.

225.110—Distribution Records

- Date, name and address of buyer, amount and name of feed, your identifier (code or whatever) and whatever else would aid in a possible recall.
- Keep one year after feed is shipped.

225.115—Complaint Files

- Record each oral and written complaint about the safety and effectiveness of the medicated feed.
- Need date, complainant's name and address, name and identification of medicated feed involved and details of complaint.
- Include copies of such items as correspondence, memorandum or conversations and descriptions of investigation and assays.
- If controlled drug is involved, check with drug supplier regarding possible required reports to FDA.

The following subparts (new additions to the GMPs) apply to those firms that do not have to register with FDA and can manufacture medicated feeds without approved Form 1900s. These firms are subject to an FDA inspection when there is reason to suspect illegal use of drugs or as a follow-up on an illegal tissue residue investigation.

Subpart F—Facilities and equipment

225.120—Buildings and grounds

- Adequate space for the manufacture of medicated feeds.

• Provide for adequate cleaning and maintenance.
• Minimize vermin and pest infestations.

225.130—Equipment

• Equipment must be suitable for its purpose.
• Scales and meters must be accurate.
• Equipment should have minimum or no carryover.

225.135—Work and storage areas

• Areas and equipment used for the manufacture of medicated feeds cannot be used to handle, mix or store fertilizers, herbicides, insecticides, fungicides, rodenticides or other pesticides (except for those approved for use in medicated feeds).

Subpart G—Product quality assurance

225.142—Components

• Identify, store and maintain inventory records on all Type A medicated articles and Type B medicated feeds.
• Potency losses must be kept to a minimum.
• Use these components in accord with label mixing directions.

225.158—Laboratory assays

• Routine assays (3 per year) are not required.
• Keep state feed control assays for one year.
• Record action taken on out-of-control assays.

225.165—Equipment cleanout procedures

• Sequence, flush or manually clean equipment to prevent drug carryover.

Subpart H—Labeling

225.180—Labeling

Labels must be accurate and have required information on them.

• Don't get them mixed up.
• Provide labels with all deliveries of feed.

Subpart I—Records

225.202—Formula, production and distribution records

• Maintain a file of formulas, production records and distribution records for one year.
• Be able to recall feeds if circumstances require it.

PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

Subpart A—General provisions

226.1—Current good manufacturing practice.

• Establishes that the following sections provide the criteria for determining whether premix manufacturers are in compliance or not.

226.10—Personnel

• Key personnel and any consultants shall have appropriate education or experience or combination to assure the integrity of the medicated premixes produced.

Subpart B—Construction and maintenance of facilities and equipment

226.20—Buildings

• Shall be maintained in a clean and orderly manner.
• Be of suitable size, construction and location for the purpose.
• Have room for orderly location of equipment and materials.
• Provide for receipt, sampling, storage and control of ingredients.
• Enable proper manufacturing and processing operations.
• Enable proper packaging and labeling.
• Provide room for containers, packing materials, labels and finished product.
• Provide room for quality control laboratory operations.
• Have enough light, ventilation, dust control, temperature control (including humidity) and other controls of the immediate environment that are necessary for maintaining purity, quality and potency of the product.
• Provide adequate washing, cleaning, toilet and locker facilities for personnel.
• Do not use this space or equipment for making or storing any pesticide unless said pesticide is an approved component of a medicated premix.

226.30—Equipment

• Shall be maintained clean and orderly.
• Shall be adequate for its purpose.
• Shall not have surfaces that affect drug components in any way.
• Be constructed so that such substances as lubricants and coolants do not become unsafe additives in any medicated premix.
• Be reasonable easy to adjust, clean and maintain.
• Be designed to prevent contamination or drug carryover.
• Be electrically grounded.
• Scales and meters be accurate enough for purpose.

Subpart C—Product quality control

226.40—Production and control procedures

• Each critical step should be performed or controlled (checked) by competent personnel.
• All containers shall be identified, handled and stored to prevent mix-ups and drug carryover.
• Equipment shall be operated and controlled to avoid contamination of components or premixes.
• Competent personnel shall compare actual yield of batches with theoretical yield—do not distribute any product having a significant discrepancy.
• Cleaning procedures shall be used to avoid drug carryover.
• Safeguards against high or low drug levels shall be used in sequential batch production.
• Provision for halting distribution must go into effect whenever product is found to be out-of-control specifications.
• Do not distribute above product until control is reestablished.

226.42—Components

• All drugs shall be received, examined or tested, stored, handled and controlled to maintain integrity, potency and identification.
• Receipt and inventory records shall show origin of drug, manufacturer's control number (if none, use invoice number), dates and batches in which used—keep for two years.
• Non-drug components shall be kept free of contamination.

226.58—Laboratory Controls

• A master record of specifications of drug components, descriptions of test procedures and statements from suppliers on analysis or specifications.
• A record of specifications for medicated premixes being produced.
• Include tests used to check those specifications.
• Assay each batch of medicated premix prepared from undiluted drug.
• Assay first five batches of medicated premix, if made from premixes assayed above, then 5% of remaining production—after an out-of-control assay, assay each batch until five consecutive batches are in control.
• Show studies that indicate uniform dispersion of drug in medicated premix and reasonable stability during shipment, storage and use. Use expiration dates, if necessary, to maintain potency of premix.
• Assay methods may be those in the "Method of Analysis of the Association of Official Analytical Chemists," those described in official compendiums or those accepted by FDA as part of a new drug application.

• Keep assays on file for two years after medicated premix has been distributed.

Subpart D—Packaging and labeling

226.80—Packaging and Labeling

• Only those medicated premixes that meet your specifications should be packaged, labeled and sold.

• Use lot or control numbers on the package or label (corresponding to the one on the production record and laboratory sample record).

• Store labels in an orderly manner.

• Check label against batch production record.

• Keep a running inventory on labels as check on correct use.

• Containers should allow safe shipping, handling and storage without loss of identity, potency or quality of medicated premix.

Subpart E—Reports and records

226.102—Master formula

• The master formula shall be prepared, endorsed and dated by a competent, responsible individual and be independently checked and approved by endorsement and date by a second competent, responsible individual.

• The master formula should have (1) the premix name and a copy of the label; (2) weight or measure of each ingredient used to make a given weight of medicated premix; (3) complete formulas for each batch size or continuous run with specific ingredients, the weight or measures of same and the theoretical yield; (4) manufacturing instructions including mixing times and control settings, if pertinent, and (5) list quality control procedures, sampling instructions, special notations and precautions that need to be followed.

226.102—Production Records

• A production record shall be prepared for each batch or run of medicated premix—keep two years after premix has been shipped.

• A production record shall have (1) identification of medicated premix, date of production and endorsement by competent, responsible individual; (2) a record of each step in manufacturing, packaging, labeling and controlling the process; (3) specific identification of drug components; (4) weights or measures of all components; (5) laboratory results; (6) mixing times; (7) endorsement of the individual performing or supervising the operation, and (8) a batch number that correlates with the lot or control number on the label.

226.110—Distribution Records

• Each shipment shall have a record of (1) date of shipment; (2) name and address of consignee; (3) quantity of each medicated premix shipped and (4) lot or control number (relating to batch number on production record). Keep two years.

226.115—Complaint Files

• Keep a record of all written or verbal complaints about the safety or efficacy of any medicated premix. Keep two years.

• Include evaluation and action taken, if any.

SUMMARY

Read the GMP regulations that follow this article. Official inspections of feed mills will provide the best interpretation of the GMPs as they are put into practice.

Feed mills that have not been inspected but who want to be able to use Type A, Category II medicated article(s) should register with FDA using Form 2656, which can be obtained from any FDA office. At the same time, obtain the applications for medicated feed approvals (Form 1900s) and submit one of these for each of the drugs wanted. These mills will be automatically inspected for compliance before an approval of the submitted Form 1900 is made. Firms having no previous inspection history will likely have some priority in inspections over those with previous inspection histories.

Firms that have failed previous inspections will have their present 1800s withdrawn through formal proceedings. Those wishing to continue using type A, Category II medicated article(s) may request reinspection after correcting the deficiencies in their operations.

attachment 1
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