The Producer: Texas Cattle Feeders Association

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I always enjoy following Dr. Crawford. He is a lot of fun and we harass each other often. We commend the approach that the FDA has taken during the last several years as far as getting out to see what is going on in the country and especially Dr. Crawford and Mr. Garner who is the Deputy Commissioner. They have been out to the feeding industry to visit with us and see what is going on. We hope we can get more of them out. We also have the same problem in that we get wrapped up in our own little world and forget what is going on outside.

Dr. McDonald forwarded the following position paper as his contribution to the Proceedings.

Position and Proposal on Second Generation of Medicated Feeds

I commend the Medicated Feed Taskforce and the Food and Drug Administration on their efforts to examine the existing medicated feed program and to recommend ways to employ resources more efficiently.

We definitely agree, as reported in the executive summary, that "Of the three basic concerns related to drugs in feed-animal safety, animal effectiveness, and human safety—the animal safety and efficacy concerns tend to be self-limiting in nature in the relatively sophisticated contemporary animal husbandry practices, because there are visual and economic factors apparent to the user of the medicated feeds."

Thus, the medicated feed program should have as its primary objective—the prevention of harmful drug residues into the human food supply by the most efficient use of FDA resources.

Changes in the Meat Animal Industry

The American meat animal industry is a dynamic and ever-changing industry. The trend toward more efficent production units, which began shortly after World War II, is based on the use of technology and automation to reduce cost and human error.

One change that has resulted is the emergence of Mixer-Feeders. A Mixer-Feeder is a producer, either a farmer of custom feeder, who mixes feed to be fed only to animals owned by him or to animals for which he has the entire responsibility—care, maintenance and management. He does not sell feed into commerce. By contrast, a Commercial Feed Manufacturer sells feed (to producers) in commerce. Therefore, government regulation should change to accomodate these two distinctly different classes—Mixer-Feeders and Commercial Feed Manufacturers.

The economic and safety considerations involved in larger Mixer-Feeder operations do not permit the use of the more dilute medicated feed articles. Technological developments over the past 10 years allow Mixer-Feeders to manufacture Type D articles directly from Type A articles, with resulting improvements in safety and efficiency of operations. This technology allows handling of drug-containing articles through a system that keeps them completely separate from other feed ingredients until the final point in the mixing of the complete feed.

The recommendations of the Taskforce reports, should they attempt to reverse this trend in the Mixer-Feeder industry, would be contributing to the defeat of the Taskforce's own objective of preventing harmful drug residues in the human food supply. The recommendations also would defeat the industry objectives of preventing residues and increasing efficiency.

Prevention of Residues

The Taskforce report is based on residue prevention by restricting access to drugs at some levels if current GMP's are not followed.

Any proposal to limit access to a drug based on concentration level would: (1) be ineffective, (2) increase production costs by use of more dilute articles, and (3) cause discriminatory regulatory practices by restricting access to drugs for one class of medicated feed mixers and not others.

FDA and USDA data indicate that the principal causes of residues will not be avoided by restricting access to drug level. The principal causes are failure to withdraw medicated feed and improper cleaning of equipment. These failures can occur regardless of the drug level. So, residue prevention by

restricted access based on drug level or concentration is not the appropriate answer and will not solve the problem of residues in food.

The impracticality of having all feed mixers of Types A, B, C and D articles subject to 512(m) is obvious. Therefore, specific controls on users by classification of intended use are more practical.

Residue Prevention Based on Intended Use

A potential risk assessment based on classification of user of medicated feeds by "intended use" as it relates to the purpose for which the feeds are produced is a more realistic and practical approach than classification by "intended use" as it relates to the drug level in the medicated feed purchased by the user.

We agree with the Taskforce Report, page 26, "that a basic concept recognized in the Act is that it is reasonable to assume that conditions prescribed, recommended, or suggested in labeling will be followed." We also recognize that data required for FDA approval of a new animal drug premix must show whether or not such drug is safe and effective for use—meaning that the finished feed is "safe and effective" for its labeled purposes.

However, the Taskforce's suggestion of classifying products by drug level is apparently based upon some classification of residue risk by misuse of the higher concentrations. This is clearly not related to the only permitted statutory criteria for a "new drug" classification. The criteria is whether the finished feed to be manufactured is "safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." Thus, potential misuse does not change the fact that there is no legal basis for granting or denying exemptions from a FD-1800 solely on the basis that a Type A or B article is used as a source of the new drug.

If FDA is concerned with misuse of the drug product and if "general recognition of safety" could legally be related to some "intended use" of the higher concentration (Type A or B) other than its use is finished feed, it would be more rational and consistent with the Act to classify such products (at any level) as "generally recognized as safe" based on: (1) facilities and methods by which they are to be diluted and (2) actual purpose for manufacturing and use of the Type D articles. This seems to be more consistent with the Act than the Taskforce's proposed system because it at least would be based upon actual "intended use" rather than misuse.

Classification Based on Intended Use

Following is a suggested system for classification by "intended use"—based on whether the purchaser of a drug product is the ultimate user of the drug or is someone who intends to manufacture an article containing the drug for purposes of re-distribution to others:

1. **Commercial Feed Manufacturer**
   a. Registration and routine inspection under 510(g) (4) and 512(m) unless specifically excluded.
   b. Compliance with current GMP's designed for Commercial Feed Manufacturers.
   c. Compliance with 512(m) unless excluded.
   d. Regulatory action based on unsafe feeds marketed in interstate commerce.

2. **Mixer-Feeder**
   a. Mixer-feeders would not be required to register under 510(g) (4) or be subject to routine inspection under Section 704.
   b. This would recognize that 512(m) was not intended for Mixer-Feeders.
   c. Regulatory action based on unsafe products introduced into interstate commerce (animals marketed).

The preceding classification—by "intended use" and regulations which apply to those uses—gives a balance of regulatory control for each classification, and it provides for the most efficient use of manpower.

The state feed control services are required to inspect, and must have the manpower to inspect, commercial feed mills. Therefore, they are readily available to assist the FDA with its inspections of commercial mills. Also, the state feed control officials are familiar with commercial mill operations.

However, state labeling regulations do not apply to Mixer-Feeders, and since this is the primary concern of states, they have no reason to inspect such mills. States do not have adequate personnel to conduct routine inspection of all Mixer-Feeders.

Also, state and federal regulations that are applicable to comercial feed manufacturers do not apply to Mixer-Feeders. That is because Mixer-Feeders are distinctly different with respect to the "intended use" of the product produced, the medicated feed.

Basically, Mixer-Feeder operations are different from those of commercial feed manufacturers; the Mixer-Feeder's operation has certain inherent safety features; and the Mixer-Feeder already is subject to regulatory action for any residue he may cause in an animal which he markets. These are some of the sound reasons for adoption of a Mixer-Feeder Compliance program, disigned sepcifically for Mixer-Feeders.

Mixer-Feeder Compliance Program

Under this proposal, Mixer-Feeders would be required to file an application if they want to be: (a) regulated under this program, (b) excluded from Registration under 510(g) (4), and (c) regulated as Mixer-Feeders under 512(m) of the Act. Compliance criteria would be included in the application filed. The FDA would do a verification inspection within

one year of filing date in order to verify that statements contained in the application were correct and equipment was suitable for measurement and mixing of the medicated feed. The Mixer-Feeder would be allowed to use the A, B and C articles from the application filing date, and he would operate on a temporary status until: (1) an FDA inspection was made and passed, **or** (2) 12 months from filing date had passed.

Mixer-Feeders approved for regulation under this compliance program would have to meet the following criteria:

1. Use A, B and C medicated feed articles to manufacture C and D articles for one species of animal.
2. Feed only animals which are owned by them or for which they have the responsibility for feeding, care, maintenance and management.
3. Do not remove the C and D finished medicated feed from their control.
4. Do not introduce into interstate commerce any drug-containing articles unless returned to manufacturer, packer, distributor or consignee complying with Section 512(a) (1) of the Act.
5. All equipment shall be of suitable size, design, construction, precision and accuracy for mixing of medicated feeds.
6. Verify the performance of the manufacturing equipment with at least one assay of medicated feed for a drug component within 30 days of initiation of manufacturing.

In the event of failure to meet requirements of Items #1 through #4, the application would be revoked immediately. In the event of failure to meet requirements of Items #5 and #6, the firm would be on probation and re-inspection would be made within 60 days. Failure on the second inspection would cause revocation of the application. This would insure that Mixer-Feeders with improved technology using A articles would be treated the same as Mixer-Feeders with conventional technology using B and C articles. It would also insure that FDA had control over the suitability of equipment used, regardless of the level of drug in the article used.

All Mixer-Feeders, including those excluded from Section 510 and regulated as Mixer-Feeder under 512(m) of the Act would be: (1) subject to inspection under Section 704 of the Act, and (2) subject to regulatory actin based on unsafe food products introduced into interstate commerce.

Inspections of Mixer-Feeders under Section 704, with the exception of certification inspections, would be limited to investigations following residue violations. Repeating violators would have their exclusion from 512(m) revoked, and would be subject to compliance with the current GMP's for Commercial Feed Manufacturers.

Summary

In conclusion, we commend the Taskforce for developing the new second generation approach to medicated feed regulations. We respectfully request that consideration be given to our proposal for a Mixer-Feeder Compliance Program. This program would permit FDA's and the State's resources to be utilized to accomplish compliance of the commercial feed industry and would not diminish benefits to consumers.