Animal Drug Lag—Where it is Today

In the past year, there have been some significant changes in the regulation of the animal health industry.

In fact, we may look back on 1982 and see that it was a turning point in the efforts to reduce drug lag, through needed reforms in the regulation of this industry.

Top officials of the Food and Drug Administration (FDA) have consistently stated that they share, with livestock producers and the animal health industry, a desire for faster drug approvals. "We at FDA . . . are aware of the economic casualties that occur when the animal health industry suffers undue and unjustified delays in drug approvals," said FDA commissioner Dr. Arthur H. Hayes, speaking before an AHI forum last year.

He continued, "I believe we can all agree that the consumer is better served by having available large numbers and a wide variety of safe and effective animals drugs."

In recent months, FDA has made a considerable effort to improve and streamline their regulatory operations. The more important changes affecting the animal health industry include:

- Consolidation of all animal drug review responsibilities in the Bureau of Veterinary Medicine (BVM). Before, review responsibilities were split between BVM and FDA's Bureau of Foods.
- Revision of the policy for new drug combinations administered in feeds, eliminating the need for drug companies to duplicate research work.
- Formulation of a policy for approval of biomass products. Reviews of these products had hit a standstill because FDA lacked a method for assessing their safety.

Still Backlog of Applications; Prolonged Approval Times

These are welcome changes, but we must put them into perspective. There is still a backlog of new animal drug applications. Approval times are still needlessly long, as illustrated by the examples of two products approved in 1982:

67 months in review—A treatment for scours in weaning pigs, apramycin sulfate (as a soluble powder for use in drinking water), lingered in review for 67 months. This is despite widespread approval and use of the product in many other countries. An additional application, submitted in December 1980 for use of the product as a feed premix, has not yet been approved.

48 months until incomplete approval—In the case of cloprostenol, a synthetic prostaglandin used to regulate the reproductive

cycle of cattle, initial approval came in a little more than 48 months. However, the approval did not include dairy cattle, a primary market for such products. That go-ahead was finally granted in late February 1983, for a total review duration of more than five years.

Three New Drugs Approved in 1982

Three new food animal drugs were approved in 1982. They represent the largest number of clearances in a single year since 1975, when five new products were approved by FDA. In the five years before 1982, FDA had approved only four new drug entitites for use in food-producing animals, for an average of less than one new product a year. Contrast that with 1967 through 1971 when the average approval rate was more than four products annually and 1972 through 1976 when it was nearly three products annually.

These statistics were first presented in 1982, in AHI's report, "The Livestock Animal Drug Lag." This report also summarized the penalties consumers and the livestock industry pay because of drug lag.

AHI concludes that drug lag:

- Deprives consumers of economic benefits from reduced costs of food production,
- Impedes efforts to reduce livestock disease,
- Delays access to proven and useful products which can improve livestock production efficiency,
- Unnecessarily increases the cost of developing and marketing new animal health products,
- Discourages animal health research and development efforts by U.S. firms,
- Reduces the efficiency of FDA personnel engaged in reviewing and approving applications for new animal drugs.

Changes Welcomed, But More Needed

The constructive changes FDA has instituted in the animal drug approval system are welcomed by the animal health and livestock industry. But many aggravating animal drug lag problems remain. Some of the regulatory reform issues AHI will concentrate on in coming months include:

- More procedural changes needed within FDA,
- Need for repeal of current restrictions on animal drug exports,
- Broader acceptance of foreign test data in applications for new animal drugs,
- Use of advisory committees to mediate industry/agency disputes. AJ

ANGUS JOURNAL Flashbacks

1971—Among the exhibitors in the Central Illinois Preview Show held June 26 were Aristocrat Angus, Platteville, Colo.; Gary Dameron, Lexington; Daniel C. Kiesewetter and Steven Kiesewetter, East Peoria; LeRoy Mindeman, LeRoy; Doug Parrett, Mahomet; L.B. Pierce & Sons, Creston; Leslie Reel, Congerville; Connie Reeser, LeRoy; Weaver Angus Farm, Peoria."