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Part VII

**Department of
Health and Human
Services**

Food and Drug Administration

Recycled Animal Waste

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 500
[Docket No. 77N-0245]
Recycled Animal Waste
AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its announced policy regarding the use of poultry litter as an animal feed ingredient. This will leave the regulation of the use of recycled animal waste to the individual States.

EFFECTIVE DATE: December 29, 1980.

FOR FURTHER INFORMATION CONTACT: Jack C. Taylor, Bureau of Veterinary Medicine (HFV-136), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION:
I. Introduction

Livestock and poultry producers, including egg-laying operations, accumulate large quantities of animal waste that present ecological and economic problems of disposal. The use of animal waste as a fertilizer is a partial solution to the disposal problem. A great deal of research has established that these animal wastes have nutrient value as an ingredient of certain animal feeds. Information available to FDA shows that edible products derived from animals receiving feeds containing recycled animal waste are indistinguishable from food products derived from animals receiving feeds not containing animal waste.

In the Federal Register of September 2, 1967 (32 FR 12714), FDA issued a statement of policy regarding the use of poultry litter as animal feed (21 CFR 500.40). It stated that FDA did not sanction the use of poultry litter as a feed or as a component of feed for animals and that poultry litter offered for animal feed use that was under the jurisdiction of the Federal Food, Drug, and Cosmetic Act would be considered adulterated within the meaning of section 402(a)(1), (a)(2)(C), and/or (a)(3) of the act. Subsequently, FDA adopted this policy for all animal waste with potential for use as an ingredient in animal feeds because the amount of information then available was not considered adequate to provide a basis for concluding that recycled animal waste is safe as a feed ingredient.

In the Federal Register of December 27, 1977 (42 FR 64662) (hereinafter cited

as the 1977 notice), FDA issued a request for submission of data, information, and views to provide additional data regarding the use of recycled animal waste as an animal feed ingredient. The notice was in response to a growing interest in the use of animal waste as an animal feed ingredient. The 1977 notice discussed in detail the information then available to FDA including the historical development of the practice of feeding waste to animals, economic and environmental considerations, human health and aesthetics, animal health, and legal considerations.

The initial comment period, which closed June 26, 1978, was subsequently extended by FDA to September 25, 1978 by notice published in the Federal Register of July 28, 1978 (43 FR 32867).

Seventy-three responses were received including 28 from university researchers and administrators, 6 from State and Federal departments of agriculture, and 7 from national societies and organizations. Many of the comments included published research and research reports that added substantially to the information previously available to the agency. This information and copies of the comments may be seen in the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857 (Docket Number 77N-0245, Recycled Animal Waste).

Since publication of the agency's policy statement, extensive research has provided a great deal of additional information. The scope of additional information comprises approximately 1,000 publications in the scientific and periodical literature.

The agency concludes from its extensive review that some processing of animal waste intended for use as a feed ingredient is necessary to minimize the possibility of harmful levels of pathogenic microorganisms that may be present in the waste. Procedures that have been used successfully as practical processing methods include dehydration, ensiling, composting, physical fractionation, fermentation, heat treatment, and addition of preservative chemicals such as formaldehyde. These treatment procedures, and the extent to which some processing of waste is mandated by practical considerations (e.g., the requirement for dehydration to reduce handling costs and difficulties and to preserve the quality of dietary components) were discussed in the 1977 notice. FDA recognizes the numerous difficulties in setting microbiological

standards for a nonuniform product subject to differing processing methods. Nevertheless, the agency emphasizes the need for processing for control of pathogens of all animal waste intended for use as a feed ingredient and encourages development by the State feed regulatory bodies of quality standards in this area.

The agency recognizes that there are questions concerning the composition of wastes and effects of processing on animal wastes which research has not yet answered. The development of research efforts to add to the information on the extent to which drug residues and possible drug metabolites are present and biologically available in recycled waste presents formidable research problems. Quantifying drug metabolites and residues would require major expenditures of resources, with the possibility of results being dependent upon variables such as recycling systems, feeding and management practices, processing methods, and animal species. Additional research in this area may or may not strengthen the basis for future judgments concerning safety.

As noted in the summary of the section on human health and aesthetics in the 1977 notice, the data available to FDA as a result of extensive literature review and provided in response to the 1977 notice do not resolve all the questions of safety that are raised by the possible occurrence of residues of drugs and drug metabolites in recycled waste. Moreover, it has become clear that such questions might not be answerable in the foreseeable future even if extensive research efforts were devoted solely to this purpose. Hence, the agency recognizes that it is necessary to weigh associated safety factors such as the levels likely to be fed, the consuming species and production classes of animals, the probability of practical withdrawal periods following feeding, and the overall extent of the practice of recycling animal wastes in this country in order to develop an assessment of the safety impact of such feeding practices. A number of these safety factors were discussed in some detail in the 1977 notice.

Additional relevant information was submitted pertaining to the extent to which animal waste feeding is now being practiced in the United States (Ref. 1). The usage level has been assessed by sending questionnaires to producers and to individuals active in animal waste management in 50 States and Puerto Rico. Other questionnaires were forwarded to the Directors of the Cooperative Extension Services in land-

grant universities. Thirty-seven responses were received, and there were indications that recycled animal waste was being used for feed to some degree in 27 of the 37 states responding. The data presented (Ref. 1), although approximate, indicate that a maximum of slightly more than 1 percent in any category of animals in production are being fed wastes as a part of their ration. The category in which the estimated usage level was approximately 1 percent was the case in which cattle waste was being fed to beef feeder cattle. From this information, it appears that the extent of use in this country of recycled animal waste as feed is very small.

II. FDA Regulatory Policy

The recycling of animal waste is primarily a local practice. The bulk and weight of the end product are such that shipment to distant places is uneconomic because of transportation costs. Thus, the use of such material is largely a local matter. For this reason, the State feed control agencies have taken the initiative in promulgating standards regarding the use of animal waste as an animal feed ingredient. Indeed, some State agencies have established programs which control the use of such waste more directly and in greater detail than would be feasible from the Federal level.

Because of the local character of animal waste use and because the States have the capacity to effectively regulate this use, FDA has decided to revoke its previous policy statement (§ 500.40 *Use of poultry litter as animal feed* (21 CFR 500.40)). The revocation of the policy statement represents a lessening of Federal regulatory intervention in favor of State control. Although FDA's regulatory action regarding recycled animal waste has been extremely limited and no enforcement actions involving this product have been brought in court, the agency believes its position should be clear. The revocation of the policy statement does not constitute a positive endorsement of the use of recycled animal waste, make any regulatory classification of waste (e.g., generally recognized as safe or food additive), or represent a concession that FDA lacks authority to regulate animal waste in the future if there exists the necessary connection with interstate commerce, e.g., interstate shipment of a component. FDA is merely stepping back from its current regulatory role in the control of animal waste. If, in the future, the agency determines that the use of recycled animal waste as a feed ingredient has ceased being largely a

local activity and that this practice presents risks to the health of animals or humans that are not controlled by State agencies, FDA will take an active role in the regulatory control of recycled animal waste.

The foregoing policy will not preclude FDA's taking regulatory action on an ad hoc basis against a particular shipment of animal waste that clearly presents a health hazard. Such action would likely be taken only if the State(s) involved were unable to take necessary action.

Comments from several States and the Association of American Feed Control Officials (AAFCO) argued persuasively for control at the State level and have expressed a willingness to superintend the commerce of animal waste used as a feed ingredient in a manner similar to that used for traditional feed ingredients. AAFCO has developed a Model Regulation for processed animal wastes and adopted this regulation in 1979 (Ref. 2). AAFCO's model regulation will enhance control at the State level to the extent that the regulation and its provisions are adopted by States where the feeding of animal wastes is practiced. In addition, regulatory uniformity will be enhanced. State feed control agencies have authority to impose various sanctions against violative feed products. For example, such products may be seized and other sanctions may be imposed by a State's refusing to permit further registration or shipment of a product. Moreover, the model regulation contains a provision that requires recordkeeping for each day's production or other identifiable lot for a period of 2 years including information on the source of the animal waste, quantity produced, sales and distribution, and assay records of testing. By monitoring these records, State feed control agencies will be able to judge the degree of acceptance and volume of use of animal waste as a commercial product.

Valuable cumulative data on the quality and composition of processed animal waste products sold commercially in California have recently been made available (Ref. 3). This publication documents California's experience since 1974 in administering that State's commercial feed license regulations regarding the sale of processed animal waste products for feed. The publication describes the procedures whereby the processing methods, quality standards, and product safety have been controlled by the State.

The AAFCO model regulation and the States with specific regulations governing animal waste usage have recognized two categories of animal

wastes: (1) those that are collected from animals that have been fed drugs, or have been tested and found to contain drug residues; and (2) those that are collected from animals that have not been fed drugs, or have been tested and found to be free of drug residues. FDA recommends that this distinction between the types of animal wastes be maintained for maximum safety. FDA encourages application of future research and State-level emphasis on testing for possible drug residues in animal waste because the agency views the use of animal waste that contains possible drug residues or metabolites with greater concern than the use of that which does not. Present consideration and future research should be directed toward the presence, accumulation, and depletion of such drugs or residues including (1) whether these substances are present in the waste products, (2) whether they are in sufficient levels to be considered unsafe or transmitted to food, and (3) if present, how processing and proper management can ensure the safety of such food products.

III. Comments

1. Several comments opposed the continued use of recycled animal waste as a feed ingredient, asserting that animal waste may contain drug residues, microorganisms that could increase transmission of disease, excessive amounts of minerals, or possibly toxic end products of metabolism.

The agency recognizes that animal waste, while also a source of nutritional value, shares the other characteristics of more traditional feed ingredients in that waste may be contaminated by undesirable microorganisms through spoilage or improper processing, or may occasionally contain elevated levels of minerals or toxic contaminants. Thus, as is true for other feed ingredients, animal waste must be monitored for contaminants as well as for nutritional values. Potential contamination problems due to industrial chemicals or pesticides, for example, would be common to both the well-known animal feed ingredients such as corn and soybean meal and the less well-known byproduct feeds and animal wastes.

2. One comment (Ref. 4) provided mineral element profiles of animal wastes and of edible tissues from cattle fed animal wastes. Samples of waste from broilers, caged layers, cattle, and swine from several regions in the United States were analyzed. Broiler litter arsenic and copper values were 54 and 441 parts per million, respectively. Dried poultry waste contained variable levels of ash, crude protein, cadmium, and

selenium, Aluminum, cadmium, and copper levels of cattle waste were higher than values reported in the literature.

Only a small amount of data on mineral content of wastes was available at the time the 1977 notice was published. The data provided by the comment are significant because they present values from a wider range of sampling than previously available. The data are directly related to and support the discussion in the 1977 notice. In that discussion, the occurrence of traces of toxic mineral elements in conventional feed constituents was described and compared with the present and potential bioaccumulation in recycled animal waste.

Excessive intake of some minerals by livestock occurs under many natural circumstances and the effect of ingestion at higher levels on tissue mineral content is variable. Levels of some minerals may be elevated in cattle waste and broiler litter when soil is incidentally included when the animal waste is collected. It has been reported that cattle may consume substantial quantities of mineral-containing soil during normal grazing, especially when grazing areas with sparse herbage (Ref. 5). The analytical level of minerals in feeds and the degree of biological absorption often do not correspond, so quantitative mineral data on feeds are often misleading in regard to extent of absorption or toxicity (Ref. 6). Information submitted in a separate comment (Ref. 7) presented evidence that the mineral content of animal waste-containing diets was not a potential hazard unless the feedstuff to which the animal waste was added contained excessive levels.

Thus, the effects on animals and edible tissues of ingestion of minerals from feeding animal waste do not appear to differ from the results of ingestion of minerals contained in other feedstuffs.

3. One comment stated that an outbreak of disease in cattle in Israel in 1977 resulted from feeding poultry litter and that *Clostridium botulinum* was the suspected cause. References from Refuah Veterinarith submitted with the comment report on the followup examination of this incident in Israel, but do not conclude that the poultry litter or faulty processing of the poultry litter was the cause of the deaths (Ref. 8). Another comment explained that the botulinum microorganism is endemic in that country, especially in southern Israel, and that this is a recurring problem with all feed ingredients, the poultry wastes presenting no more of a problem than other feeds (Ref. 8).

In Israel, animals in some places are periodically vaccinated to prevent botulism outbreaks. A large amount of controlled testing has been carried out with animal wastes in Israel. Sterilization by heat treatment and ensiling are extensively used for processing. The officially sanctioned use of animal wastes in feedmills began in 1972. At the time of the botulism outbreak in 1977, it has been estimated that 15,000 to 18,000 tons of heat sterilized waste and 3 to 4 times this amount of ensiled and other types of poultry waste were being fed annually. After the outbreak of botulism and followup investigations, the feeding of wastes to cattle in Israel was resumed.

4. One comment submitted extensive information on the presence and survival of *Leptospira* in animal waste (Ref. 9). Leptospirosis is a contagious disease of animals and man due to infection with *Leptospira spp.* Following acute infections, the organisms localize in the kidney and may be excreted in the urine for months or years. If infected shedder animals are introduced into a herd which has been free of the disease, leptospirosis is rapidly disseminated through physical contact or, by the most common mode, from contact with urine or contaminated feed or water. Control is usually achieved by fencing the herd from surface waters, by rodent depopulation, or by vaccination of animals.

Studies have been conducted on leptospiral survival in cattle manure and the possibilities of an animal health problem from this source (Ref. 9). Specifically, information using a model oxidation ditch treatment system has been reported. In this model, hamsters susceptible to leptospiral infection were exposed to aerosols from aerated cattle manure under oxidation ditch conditions and also fed recycled feed which had been suspended in a contaminated slurry. Hamsters exposed to the ambient air of the oxidation ditch and hamsters fed the recycled feed were serologically and culturally negative to leptospiral infection. However, *Leptospira* were detected surviving in the model oxidation ditch for at least 136 days. *Leptospira* isolated from the slurry of the model oxidation ditch 17 days after seeding lost measurable virulence, so there is a possibility that the disease-transmission factor or virulence is reduced by the aerobic slurry environment.

The effects of treatment systems other than oxidation ditch methods on leptospiral pathogens are not available. Investigators are considering methods to efficiently and economically process

animal wastes for disease control. For example, ensiling, deep-stacking, heat treatment, and use of chemicals have been investigated (Ref. 10). As this problem becomes better defined, it may be possible to determine the extent to which the feeding of recycled waste contributes to the transmission of this pathogen and the extent to which transmission may differ from that accepted for land application or other means of waste disposal.

The oxidation ditch method of enhancing the protein quality of waste has been used very little, and then primarily for experimental purposes. Most pathogenic organisms do not compete effectively in an oxidation ditch (Ref. 10), and few have been observed as health problems. Price increases of electrical power for mechanically aerated liquid manure as in the oxidation ditch method have reduced interest in the aerobic treatment of livestock manure (Ref. 11).

5. A comment stated that further studies should be made of the male hormone content of animal waste products and of the possible adverse or beneficial effects of feeding animal waste to other animals (Ref. 12). The comment cited research published during the years 1947 to 1956 showing that dried manure from female ruminant animals induced an androgenic response when fed to chicks. The authors suggested that progesterone might be converted by microorganisms in the rumen into androgens, since fecal androgenic activity seemed to be related to endogenous and exogenous progesterone metabolism. Parallel studies have been conducted (Ref. 13) to determine the kind and amount of hormonal activity present in poultry excreta processed for use as livestock feed. These more recent studies indicated that caged laying hen excreta under certain processing conditions contained androgenic activity that ranged from 2.2 to 7.4 micrograms of testosterone equivalents per gram of dried excreta. This activity was not present in fresh excreta. The information reported suggests that a metabolite may be converted to androgens by bacteria in the manure, and that the androgenic activity is not eliminated by subsequent heating.

In the years since the early work was reported there has been very little information on the subject of hormonal activity in waste, and no additional information was supplied by the comments submitted in response to the agency's request for data, information, and views. Hormonal activity was not, however, identified as a problem in

reviews of the health aspects of feeding animal waste (Refs. 14 and 15) or in the numerous research articles received by the agency during the comment period. The early research has apparently not been confirmed with regard to practical significance. The agency is unable to conclude from the information in this comment or from the information submitted to the agency that there is a safety problem due to androgenic activity in waste.

6. A comment expressed concern that avian tuberculosis could be transmitted to swine as a result of swine coming into contact with chicken excreta (Ref. 16). The comment referenced supporting documentation (Ref. 17) printed since publication of the agency's 1977 notice. The supporting documentation did not specifically refer to poultry waste, but to the general subject of disease transfer to swine.

Relevant information on disease-producing bacteria in animal waste was discussed in the 1977 notice. Limited information concerning processing that would inactivate mycobacteria was referenced. In addition, the general discussion in the 1977 notice of microbiological contamination as related to human health is applicable. The concerns of the agency in regard to proper processing of animal waste that may be recycled were expressed as a part of that discussion.

Information recently received by the agency from the United States Department of Agriculture (Meat and Poultry Inspection, Food Safety and Quality Service) indicates that the rate of condemnation due to avian tuberculosis in mature poultry (includes both heavy and light hens) has been 0.01 percent or less in recent years; the disease has therefore practically been eradicated from national flocks. Lesions of this disease are not found at all in broiler chickens which constitute by far the largest portion of commercial flocks in this country.

In any event, as explained in the 1977 notice, the feeding of waste from chickens to swine would typically never occur, or occur only rarely, since the uric acid nitrogen in the chicken waste is not useable by swine. Because of the high fiber content and the nonprotein nitrogen in poultry waste, the material can readily be used by ruminants, but not by nonruminants. Swine, as nonruminants, require a source of preformed protein for efficient utilization of feed ingredients.

The agency concludes that the potential for infection of swine with mycobacteria from properly processed chicken waste is small. Research projects are underway, however, to

investigate the degree of freedom from microbiological contamination that can be achieved by ensiling and other processing methods (Ref. 18).

7. One comment stated that there were questions concerning transfer of R-plasmids in enteric microorganisms when animal waste was recycled (Ref. 19).

Experimental studies which relate the effect of recycling animal waste to antibiotic resistance in enteric bacteria are not known to the agency. Animal wastes may contain antibiotics, as described in FDA's 1977 notice, because a large percentage of all animal feeds contain antibiotics which are included to increase the rate of weight gain and to improve feed efficiency.

It is recognized that plasmid-mediated or R-factor resistance is the most significant form of antibiotic resistance. In the 1977 notice, the agency did not discuss R-factor resistance in relation to antibiotics in animal wastes because the circumstance of antibiotic resistance appears to involve the entire spectrum of animal feeding as well as human and animal therapeutic treatment. It was not, therefore, considered to be particularly related to animal waste utilization.

No information has been received since 1977 which would lead the agency to conclude that the presence of such antibiotics or possibly antibiotic-resistant bacteria in animal waste would present any more of a problem than is usual in mixed feeds for animals, which may contain similar amounts of antibiotics and antibiotic-resistant organisms (Refs. 20 and 21).

8. One comment noted that there was an incorrect entry on page 64669 of the 1977 notice, that the statement, "data collected indicated that treatment of cattle waste with 0.74 percent formaldehyde solution destroys microbial activity and prevents mold growth for a minimum of 3 months" should read " * * * prevents mold growth for up to 3 months."

The agency agrees with the comment which is supported by reference number 5 cited in the 1977 notice. Because the statement as published in the Federal Register was only one of many in the broad discussion of numerous preservation and treatment techniques, it would not materially alter the general nature of the discussion or any subsequent agency conclusions concerning the subject.

References.

1. Comment C-21, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the Federal Register of December 27, 1977; 42 FR 64662. Survey of extent of use of animal

waste feeding in the United States. Hewins, S. O., *Health and Other Considerations of Animal Refeeding as an Alternative to Animal Waste Disposal*, M.S. Thesis, University of North Carolina, Chapel Hill, 143 pp., 1977.

2. Association of American Feed Control Officials, Inc., Official Publication, pp. 198-201, 1979.

3. Helmer, J. W., "Monitoring the Quality and Safety of Processed Animal Waste Products Sold Commercially as Feed," *Journal of Animal Science*, 50(2):349, 1980.

4. Comment RPT-03, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the Federal Register of December 27, 1977; 42 FR 64662. Information on Mineral Element Profiles of Animal Wastes and Edible Tissues from Cattle Fed Animal Wastes.

5. Thornton, I., "Biogeochemical and Soil Ingestion Studies in Relation to the Trace-element Nutrition of Livestock," in W. G. Hoekstra, J. W. Suttie, H. E. Ganther and W. Mertz (Eds.), *Trace Element Metabolism in Animals-2*, University Park Press, Baltimore, 1974.

6. Underwood, E. J., *Trace Elements in Human and Animal Nutrition*, 4th ed., Academic Press, New York, pp. 1-12, 472-478, 1977.

7. Comment C-41, received in response to Recycled Animal Waste, Request for Data, Information, and Views published in the Federal Register of December 27, 1977; 42 FR 64662. Comment comparing mineral content of recycled animal waste and original feedstuffs.

8. Comments C-37, C-49, and RPT-07, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the Federal Register of December 27, 1977; 42 FR 64662. Information on a botulism outbreak in Israel.

9. Comment REF-02, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the Federal Register of December 27, 1977; 42 FR 64662. Information concerning the survival of pathogens in animal manure; Environmental Protection Agency Report 660/2-75-012.

10. Day, D. L. and B. G. Harmon, "A Recycled Feed Source from Aerobically Processed Swine Wastes," *Transact. American Society of Agricultural Engineers*, 17(1):82, 1974.

11. Comments C-33 and C-42, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the Federal Register of December 27, 1977; 42 FR 64662. Information submitted on aerobic processing by oxidation ditch methods.

12. Comment C-27, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the Federal Register of December 27, 1977; 42 FR 64662. Information and research article citations concerning hormonal activity in cattle waste.

13. Calvert, C. C., L. W. Smith, and T. R. Wrenn, "Hormonal Activity in Poultry Excreta Processed for Livestock Feed," *Poultry Science*, 57(1):265, 1978.

14. Fontenot, J. P. and K. E. Webb, "Health Aspects of Recycling Animal Wastes by

Feeding," *Journal of Animal Science*, 40:1267, 1975.

15. Bhattacharya, A. N. and J. C. Taylor, "Recycling Animal Waste as a Feedstuff," *Journal of Animal Science*, 41(5): 1438, 1975.

16. Comment MT-01, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the *Federal Register* of December 27, 1977; 42 FR 64662. Telephone communication concerning tuberculosis in swine.

17. Baker, R. (ed.), "Tuberculosis" *Maryland Agri-Views*, Maryland Department of Agriculture, Annapolis, Vol. 5, No. 1, p. 1, August 1978.

18. Comment RPT-04, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the *Federal Register* of December 27, 1977; 42 FR 64662. Information on research plans of S-139 Regional Technical Committee in regard to animal health and food safety aspects of feeding animal wastes.

19. Comment C-22, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the *Federal Register* of December 27, 1977; 42 FR 64662. Comment relating concern about transfer of R-plasmids in microorganisms.

20. Hartley, C. L., K. Howe, A. H. Linton, K. B. Linton, and M. H. Richmond, "Distribution of R-Plasmids Among the O-Antigen Types of *Escherichia coli* Isolated from Human and Animal Sources," *Antimicrobial Agents and Chemotherapy*, 8:122-131, 1975.

21. Huber, W. G., D. Korica, T. P. Neal, P. R. Schnurrenberger, and R. J. Martin, "Antibiotic Sensitivity Patterns and R-Factors in Domestic and Wild Animals," *Archives of Environmental Health*, 22:561-567, 1971.

IV. Environmental Impact

The agency has determined pursuant to 21 CFR 25.24 (b)(5) and (b)(11) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

§ 500.40 [Removed]

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 402(a) (1), (2)(C), and (3) and 701(a), 52 Stat. 1046 as amended, 52 Stat. 1055 (21 U.S.C. 342(a) (1), (2)(C), and (3) and 371(a))) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 500 is amended by removing §500.40 *Use of poultry litter as animal feed*.

Effective date. This revocation is effective December 29, 1980.

(Secs. 402(a) (1), (2)(C), and (3) and 701(a), 52 Stat. 1046 as amended, 52 Stat. 1055 (21 U.S.C. 342(a) (1), (2)(C), and (3) and 371(a)))

Dated: December 17, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

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