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in the dog indicate it is excreted in the urine essentially as leukomethylene blue stabilized in some manner. Methylene blue itself is stepwise demethylated in alkaline solutions (alkaline urine being a frequent consequence of urinary infection) to Azure B, Azure A, and Azure C. The antiseptic efficacy of all of these excretion products is unsubstantiated.

(3) In view of the foregoing, the Commissioner has concluded that animal drugs containing methylene blue for oral use in cats or dogs are neither safe nor generally recognized as effective within the meaning of section 201(v) of the act and are therefore considered new animal drugs. Accordingly, all prior formal and informal opinions expressed by the Food and Drug Administration that such drugs are ''not new drugs'' or ''no longer new drugs'' are hereby revoked.

(b) Animal drugs that contain methylene blue for oral use in cats or dogs and not the subject of an approved new animal drug application (NADA) are deemed to be adulterated under the provisions of section 501(a) (5) and/or (6) and/or misbranded under section 502(a) of the act and subject to regulatory action as of April 10, 1978.

(c) Sponsors of animal drugs that contain methylene blue for oral use in cats or dogs and not the subject of an approved new animal drug application (NADA) may submit an application in conformity with § 514.1 of this chapter. Such applications will be processed in accordance with section 512 of the act. Submission of an NADA will not constitute grounds for continued marketing of this drug substance until such application is approved.

(d) New animal drug applications required by this regulation pursuant to section 512 of the act shall be submitted to the Food and Drug Administration. Center for Veterinary Medicine, Office of New Animal Drug Evaluation (HFV-100), 7500 Standish Pl., Rockville, MD 20855.

[43 FR 9803, Mar. 10, 1978; 43 FR 12310, Mar. 24, 1978, as amended at 54 FR 18279, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992; 60 FR 38480, July 27, 1995]

### § 500.29 Gentian violet for use in animal feed.

The Food and Drug Administration has determined that gentian violet is not generally recognized as safe for use in animal feed and is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act), unless it is intended for use as a new animal drug, in which case it is subject to section 512 of the act. The Food and Drug Administration has determined that gentian violet is not prior sanctioned for any use in animal feed.

[56 FR 40506, Aug. 15, 1991]

### § 500.30 Gentian violet for animal drug use.

The Food and Drug Administration (FDA) has determined that gentian violet is not generally recognized as safe and effective for any veterinary drug use in food animals and is a new animal drug subject to section 512 of the Federal Food, Drug, and Cosmetic Act. FDA has determined that gentian violet is not exempted from new animal drug status under the ''grandfather'' provisions of the Drug Amendments of 1962 (21 U.S.C. 342).

[56 FR 40507, Aug. 15, 1991]

### § 500.35 Animal feeds contaminated with Salmonella microorganisms.

(a) Investigations by the Food and Drug Administration, the Centers for Disease Control of the U.S. Public Health Service, the Animal Health Division of the Agricultural Research Service, U.S. Department of Agriculture, and by various State public health agencies have revealed that processed fish meal, poultry meal, meat meal, tankage, and other animal byproducts intended for use in animal feed may be contaminated with Salmonella bacteria, an organism pathogenic to man and animals. Contamination of these products may occur through inadequate heat treatment of the product during its processing or through recontamination of the heat-treated product during a time of improper storage or handling subsequent to processing.

(b) Articles used in food for animals are included within the definition of

*food* in section 201(f) of the Federal Food, Drug, and Cosmetic Act. Further, Salmonella contamination of such animal feeds having the potentiality for producing infection and disease in animals must be regarded as an adulterant within the meaning of section 402(a) of the act. Therefore, the Food and Drug Administration will regard as adulterated within the meaning of section 402(a) of the act shipments of the following when intended for animal feed and encountered in interstate commerce and found upon examination to be contaminated with Salmonella microorganisms: Bone meal, blood meal, crab meal, feather meal, fish meal, fish solubles, meat scraps, poultry meat meal, tankage, or other similar animal byproducts, or blended mixtures of these.

[40 FR 13802, Mar. 27, 1975, as amended at 54 FR 18279, Apr. 28, 1989]

### § 500.45 Use of polychlorinated biphenyls (PCB's) in the production, handling, and storage of animal feed.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption (meat, milk, and eggs). Investigations by the Food and Drug Administration have revealed that heat exchange fluids for certain pasteurization equipment used in processing animal feed contain PCB's. Although heat exchange fluids in such equipment are considered to be in *closed systems*, leakage has occurred that resulted in direct contamination of animal feed with PCB's and subsequently resulted in the transfer of PCB's to human food produced by animals consuming the contaminated feed. The use of PCB-containing coatings on the inner walls of silos has resulted in the contamination of silage which has in turn caused PCB residues in the milk of dairy cows consuming the contaminated silage. Since PCB's are toxic chemicals, the PCB contamination of food as a result of these and other incidents represent a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of animal feed.

(b) The following special provisions are necessary to preclude accidental PCB contamination of animal feed:

(1) Coatings or paints for use on the contact surfaces of feed storage areas may not contain PCB's or any other harmful or deleterious substances likely to contaminate feed.

(2) New equipment or machinery for handling or processing feed in or around an establishment producing animal feed shall not contain PCB's.

(3) On or before Sept. 4, 1973, the management of establishments producing animal feed shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling and processing feed sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices, be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the animal feed producing establishment any PCB-containing lubricants for equipment or machinery used for handling or processing animal feed.