⟨1152⟩ ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

PURPOSE

This chapter provides general descriptions of, and definitions for, animal drugs and drug products delivered in animal feeds. It discusses general principles involved in the manufacture, packaging, and labeling of these drugs and drug products.

SCOPE

Medicated articles and feeds that are used to deliver animal drug(s) via the food given to animals are discussed in this general information chapter. Drugs approved for further manufacture into medicated animal feeds are not dosage form drugs. Dosage form drugs administered with feeds are not medicated articles or feeds. Drug dosage forms are listed in *USP* general chapter *Pharmaceutical Dosage Forms* ⟨1151⟩.

Animal drugs approved for further manufacture into medicated animal feeds may be in either dry or liquid form. They are sometimes referred to as premixes. The term "premix" is no longer used for animal drugs for use in animal feeds but is still used in some older drug monographs. Animal drugs in feeds are regulated as Type A medicated articles and Type B and Type C medicated feeds.

Type A Medicated Articles

Type A medicated articles [21 CFR 558.3(b)(2)] are concentrated forms of animal drugs intended solely for further manufacture of other approved Type A medicated articles or Type B or C medicated feeds. This means that Type A medicated articles cannot be fed directly to animals. They consist of one or more animal drug(s) with or without a carrier (e.g., calcium carbonate, rice hull, corn, gluten) and with or without other inactive ingredients. They can be prepared in dry or liquid form. They are sold to feed mills or livestock producers and are intended to be further diluted by mixing into feed before consumption by animals.

Type B Medicated Feeds

Type B medicated feeds [21 CFR 558.3(b)(3)] are intermediate medicated feeds for animals. They are manufactured from either Type A medicated article(s) or other Type B medicated feed(s) by dilution with non-medicated feed ingredients. In addition to the animal drug(s), Type B medicated feeds contain a substantial quantity of nutrients that comprise NLT 25% of the total feed weight. They can be prepared in dry or liquid form. Similar to Type A medicated articles, Type B medicated feeds are intended only for further dilution by mixing into feed, and they are not approved for feeding to animals.

Type C Medicated Feeds

Type C medicated feeds [21 CFR 558.3(b)(4)] are intended to be fed directly to animals. They are manufactured from Type A medicated articles, Type B medicated feeds, or other Type C medicated feeds diluted with non-medicated feed ingredients. Type C medicated feeds may be prepared in dry or liquid form. Type C medicated feeds can be either fed as the complete feed for the animals, top-dressed onto the animals' normal daily rations, or offered "free-choice" (21 CFR 510.455). Type C medicated feeds approved to be offered free-choice are not intended to be fully consumed in a single feeding or to constitute the entire diet of the animals.

PREPARATION

Type A medicated articles in dry form are typically produced by blending the drug substance(s) with carriers and other excipients to promote uniform mixing when subsequently added to the animal feed. The drug substance(s) may first be mixed with an excipient (e.g., starch or sodium aluminosilicate) that has a similar particle size and can help distribute the drug substance(s) uniformly throughout the final mixture. This pre-blend may then be mixed with bulk excipients (e.g., calcium carbonate or soybean hulls). The product may be granulated and/or oil (e.g., mineral oil, soybean oil) may be added to aid uniform distribution, to prevent particle segregation during shipping, and/or to minimize formation of airborne drug substance particles during production of another Type A medicated article or Types B or C medicated feeds.

Type A medicated articles in liquid form are produced by mixing the drug substance(s) with a suitable solvent (e.g., water or propylene glycol). The drug substance(s) is usually dissolved to produce a solution, but suspension products could be produced also.

Types B or C medicated feeds are typically manufactured at feed mills or on-farm by livestock producers. To manufacture Types B or C medicated feeds in dry form, Type A medicated articles are added to the feeds during the mixing process. Liquid Type A medicated articles may be sprayed in at set rates, and dry Type A medicated articles are added using methods that facilitate uniform distribution in the feeds. Types B and C medicated feeds in dry form may be further processed by heating, steaming, and extruding into pellets. The pellets may be rolled or broken up to create crumbles. Types B and C medicated feeds may also be prepared in liquid form. Liquid feeds are typically molasses based and contain an animal drug(s) dissolved or suspended in the liquid matrix. The liquid feed may need to be recirculated or agitated on a routine basis to maintain a uniform distribution of the drug(s).

A Type B medicated feed may also be prepared by diluting another Type B medicated feed. A Type C medicated feed may also be prepared by diluting a Type B medicated feed or another Type C medicated feed.

LABELING AND PACKAGING

Labeling for Type A medicated articles and Types B and C medicated feeds provides all information necessary for their safe and effective use. The label for a Type A medicated article includes mixing directions for the manufacture of medicated feeds from the Type A medicated article and feeding directions for the Type C medicated feeds. The label for a Type B medicated feed provides mixing directions for the manufacture of medicated animal feeds. Labels for both Type A medicated articles and Type B medicated feeds indicate that they are not to be fed directly to animals. The label for Type C medicated feeds includes directions for feeding.

Type A medicated articles are packaged in bags (e.g., paper with polyethylene liners) for dry products or in appropriate containers (e.g., plastic) for liquids. Typical sizes are 50-lb bags or several-gallon containers. Dry Types B and C medicated feeds may be packaged in bags for storage and delivery, or they may be shipped in bulk form for storage or immediate use. Free-choice Type C medicated feeds may be packaged in bags (e.g., loose minerals), wrapped in film (e.g., compressed blocks), or packaged in tubs (e.g., molded blocks). Liquid Types B and C medicated feeds are stored and shipped in bulk in tanks.

NOMENCLATURE

The drug product's established (non-proprietary) name consists of the drug substance (active moiety) and an appropriate type of medicated article or feed. The following nomenclature options are available to indicate types of medicated articles or feeds as part of the product established name:

[Drug] Type A medicated article
[Drug] Type A liquid medicated article
[Drug] Type B medicated feed
[Drug] Type B liquid medicated feed
[Drug] Type C medicated feed
[Drug] Type C liquid medicated feed
[Drug] Type C free-choice medicated feed
[Drug] Type C liquid free-choice medicated feed
[Drug] Type C top-dress medicated feed