USDA United States Department of Agriculture
Foreign Agricultural Service

GAIN Global Agricultural Information Network

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# **Report Name:** Philippine Food and Drug Administration Clarifies Jurisdiction on Veterinary Drug Products

**Country:** Philippines

**Post:** Manila

**Report Category:** FAIRS Subject Report, Food and Agricultural Import Regulations and Standards - Certification, Grain and Feed

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**Report Highlights:**

The Philippine Food and Drug Administration (PFDA) reiterated its jurisdiction on the regulation of veterinary drug products. The PFDA clarified that it shall regulate finished products for therapeutic purposes for animals, including veterinary drugs, medicated feed products, and antimicrobials. The PFDA has yet to issue specific guidelines for veterinary drugs. Meanwhile, it currently adopts Health Canada's guidance document in classifying veterinary drugs and feed products. The Philippine Department of Agriculture's Bureau of Animal Industry also continues to regulate animal feed products.

The Philippine Food and Drug Administration (PFDA) issued Advisory No. 2024-1082 on August 5, 2024, reiterating its jurisdiction on veterinary drug products. The PFDA shall regulate finished products for therapeutic purposes for animals, including veterinary drugs, medicated feed products, and antimicrobials. In this context, the PFDA issues a License to Operate (LTO) for local establishment before it can manufacture, import, export, sell, distribute, transfer, promote, advertise and/or sponsor an activity involving veterinary drug products and veterinary biologics. It likewise issues certifications, including a Certificate of Product Registration (CPR) for both locally manufactured and imported products under its jurisdiction.

The PFDA currently adopts Health Canada's guidance document in classifying veterinary drugs and feeds, while detailed guidelines on veterinary drug products have yet to be prepared. In general, a product administered orally via gavages or drenches (forceable administration), contains a known medicinal ingredient, and/or indicates therapeutic claims is considered a drug and thereby subject to PFDA's regulations. The PFDA's Advisory also notes that if one of the drug criteria is met (Table 1), the ingredient or product would be classified as a drug and subject to its jurisdiction.

**Table 1. Criteria for Veterinary Drug and Feed Classification**

| Feed | Drug |
|---|---|
| Diet deficiency | Abnormal requirement from animal (deficiency due to disease state) |
| Interference between nutrients in diet | Lack of absorption from the body (due to disease state) |
| Physiological (normal) increase in animal requirements (e.g. parturition, lactation, sweating) | Abnormal requirement from animal (secondary to disease) (i.e. dehydration following diarrhea, bicarbonate in the presence of metabolic acidosis) |
| Relevant species (species with recognized nutritional need) | Species with no recognized deficiency or dietary requirement |
| Ingredients from approved and recognized feed source of vitamin/mineral | New source may have other properties or purposes |
| Scientific data supporting a nutritional purpose for a specific nutrient | Scientific data supporting a therapeutic (drug) purpose for a specific nutrient |

Source: PFDA

Meanwhile, the Philippine Department of Agriculture's Bureau of Animal Industry (BAI) regulates feed ingredients, feed additives, or feed raw materials intended for manufacturing or production of animal feeds. Prior to starting its business operations, a local feed establishment (e.g., feed manufacturer, feed

ingredient manufacturer, importer, exporter, supplier, distributor, and retailer) needs to secure an LTO from BAI. The licensed feed establishment is also required to have a Certificate of Feed Product Registration (CFPR) for the marketing, importation, distribution, selling, and use of BAI-regulated animal feed products, such as feed ingredients and finished feeds.

Key Philippine regulations and basic importation procedures related to international trading of food and agricultural products, including animal feed, are contained in FAS Manila's Food and Agricultural Import Regulations and Standards (FAIRS) Report. A local company/importer usually assists a potential exporter in navigating the CPR or CFPR process. Additionally, the BAI and PFDA likewise have their respective Citizen's Charter, containing step-by-step procedures, documentary requirements, timelines, and fees to be paid for the processing and issuance of pertinent licenses and certifications (Table 2).

**Table 2. Citizen's Charter and Contact Information of PFDA and BAI**

| Regulatory Agency | Detailed Process | Contact Information |
|---|---|---|
| Food and Drug Administration | Citizen's Charter 2024<br>• Issuance of LTO<br>• Issuance of CPR of drug products for human and veterinary use under FDA-Center for Drug Regulation and Research External Services | Email: info@fda.gov.ph<br>Tel: +632 8 857-1900<br>Website: https://www.fda.gov.ph/ |
| Bureau of Animal Industry | Citizen's Charter 2024<br>• Issuance of LTO and CFPR under BAI-Animal Feeds, Veterinary Drugs and Biologics Control Division | Email: afvdbcd@bai.gov.ph<br>Tel: +632 8 528-2240<br>Website: https://www.bai.gov.ph/ |

Source: PFDA and BAI

**Attachments:**

No Attachments.