DR. MARIA ROSARIO S. VERGEIRE
Officer-in-Charge
Department of Health
Rizal Avenue, Sta. Cruz, Manila

Dear OIC Secretary Vergeire:

This has reference to your request for this Department’s opinion on the regulatory jurisdiction of the Food and Drug Administration (FDA) under the Department of Health (DOH) and the Bureau of Animal Industry (BAI) of the Department of Agriculture (DA) over veterinary drug products.

It appears that both agencies claim regulatory authority over veterinary drug products\(^1\) and establishments. The issue stemmed from the draft Joint Memorandum Circular (JMC) proposed by the Department of Agriculture (DA) that will cover all veterinary drugs, products, and establishment, in effect seeking to re-adopt the Joint DOH and DA Administrative Order (JAO) No. 2013-0026, providing the “Rules on the Regulation of Veterinary Drugs and Products, Veterinary Biological Products, and Veterinary Drug Establishment”, which expired on 24 September 2018\(^2\). While JAO No. 2013-0026 was re-adopted for another six months or until 28 February 2021\(^3\), said period was intended only as a transition period for the transfer of regulation of veterinary drugs, biologicals, and establishments to the FDA. Thereafter, FDA will immediately assume such functions.

Antecedent Facts

The FDA was established under the DOH by virtue of Republic Act (R.A.) No. 3720 or "Food, Drug, and Cosmetic Act"\(^4\) on June 22, 1963\(^5\) to ensure safe and good quality

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\(^1\) On 21 February 2021, this Department received a request from then Secretary of Agriculture William A. Dar seeking clarification on the regulatory jurisdiction of the FDA over veterinary biological products. This opinion consolidates the response to both queries as it involves the same parties and issues.

\(^2\) Paragraph XI, JAO No. 2013-0026

\(^3\) JAO No. 2020-001, 27 August 2020

\(^4\) "AN ACT TO ENSURE THE SAFETY AND PURITY OF FOODS, DRUGS, AND COSMETICS BEING MADE AVAILABLE TO THE PUBLIC BY CREATING THE FOOD AND DRUG ADMINISTRATION WHICH SHALL ADMINISTER AND ENFORCE THE LAWS PERTAINING THERETO"

\(^5\) R.A. No. 3720, Chapter III, Section 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration in the Department of Health. xxx
supply of food, **drug**, and cosmetic, and to **regulate** the production, sale, and traffic of the same to protect the health of the people.\(^6\)

In 1987\(^7\), Executive Order (E.O.) No. 175 renamed the FDA to Bureau of Food and Drugs (BFAD) and strengthened its regulatory power over drugs, to include **new veterinary drugs**. It is under this law that "new veterinary drugs" were first introduced and defined as –

(w) "New veterinary drugs" means drugs intended for use for animals including any drug intended for use in animal feeds but not including animal feeds within the contemplation of the implementing rules and regulations.\(^8\)

In 2009\(^9\), R.A. No. 9711 was enacted reverting the name of BFAD to FDA and expressly providing for the following objectives in creating the FDA. To enumerate:

Section 4. This Act has the following objectives:

(a) To enhance and strengthen the administrative and technical capacity of the FDA in the **regulation of establishments and products under its jurisdiction**;

(b) To ensure the FDA's monitoring and **regulatory coverage over establishments and products under its jurisdiction**; and

(c) To provide coherence in the FDA's **regulatory system for establishments and products under its jurisdiction**.

On the other hand, the BAI, was created pursuant to R.A. No. 3639 under the Department of Agriculture and Natural Resources (now the Department of Agriculture). Under the Administrative Code\(^1\), the BAI is mandated to promote the development of livestock, poultry, and **allied industries** and ensure the country's food sufficiency. Its functions and authority is clearly enumerated in Section 18, Book IV, Title IV, Chapter 4 thereof as follows –

**CHAPTER 4**
Bureaus and Offices

**SECTION 18.** Bureau of Animal Industry – The Bureau of Animal Industry shall:

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\(^6\) *Ibid*, Section 2. It is hereby declared the policy of the State to insure safe and good quality supply of food, drug and cosmetic, and to regulate the production, sale, and traffic of the same to protect the health of the people.

\(^7\) 22 May 1987

\(^8\) Section 10(w), R.A. 3720, as amended by E.O. No. 175

\(^9\) 18 August 2009

\(^1\) E.O. No. 292
(1) Formulate programs for the development and expansion of the livestock, poultry, and dairy industries to meet the requirements of the growing populace;

(2) Recommend the specific policies and procedures governing the flow of livestock products through the various stages of marketing, as well as the proper preservation and inspection of such products;

(3) Coordinate and monitor the activities and projects relating to livestock and allied industries;

(4) Prescribe standards for quality in the manufacture, importation, labelling, advertising, distribution, and sale of livestock, poultry, and allied industries; and

(5) For its own sector, recommend plans, programs, policies, rules and regulations to the Secretary and provide technical assistance in the implementation of the same.

Under Section 26 (f) of R.A. No. 3720, as amended, the Secretary of Health was authorized to call on the assistance of any department, office, or agency for the effective implementation of the law\textsuperscript{15}, hence, BFAD (now FDA) entered into a Memorandum of Agreement (MOA) with the BAI to regulate veterinary drugs, among others.

On 24 September 2013, the MOA was revalidated with the issuance of JAO No. 2013-0026\textsuperscript{16} between DOH and DA. The JAO expired in September 2018\textsuperscript{17}.

In 2020\textsuperscript{18}, the DOH and DA issued JAO No. 2020-0001 re-adopting JAO No. 2013-0026 for a period of six (6) months from the issuance thereof to ensure unhampere
delivery of services to the stakeholders. This six-month period will serve as the transition period for the transfer of regulation of veterinary drugs, biologicals, and establishments to the FDA. As previously stated, after the transition period, FDA will immediately assume the regulation of veterinary drugs, biologicals, establishments without the need of further orders or issuances. Notwithstanding, the BAI asserts its regulatory jurisdiction over veterinary drugs with the proposed JMC.

\textit{Issue}

Whether the BAI has regulatory jurisdiction over veterinary drugs products and establishments.

\textsuperscript{15} Sec. 19. Section 26 of Republic Act No. 3720 is hereby amended to read as follows:

"E.O. No. 175, Sec. 26. Xxxx

(f) The Secretary is hereby authorized to call on the assistance of any Department, Office or Agency for the effective implementation of the provisions of this Act."

\textsuperscript{16} Rules on the Regulation of Veterinary Drugs and Products, Veterinary Biological Products, and Veterinary Drug Establishments

\textsuperscript{17} JAO No. 2013-0026, XI. EFFECTIVITY AND DURATION

\textsuperscript{18} 27 August 2020
Discussion

We advise that BAI has no regulatory jurisdiction over veterinary drugs products and establishments. The authority to regulate veterinary drug products and establishment fall within the purview of the FDA. This authority includes the right to inspect, license, register, monitor, and conduct post-market surveillance of drugs, including veterinary drugs, to ensure their safety, potency, and quality.

The BAI's primary mandate is to ensure food sufficiency by formulating programs to develop, and prescribing standards for quality in the manufacture, importation, labelling, advertising, distribution, and sale of, livestock, poultry, and allied industries. Its regulatory authority over these products emanated from R.A. No. 1556 (Livestock and Poultry Feeds Act), which designated the BAI as its chief enforcing official.

Section 3 (c) of R.A. No. 1556 defines livestock to include horses, cattle carabaos, sheep, goats, swine, rabbits, poultry and such other animals or birds as the Secretary may, from time to time by regulation, prescribe. For further clarity, subsequent related issuances categorically states that livestock refers to food animals and that poultry is included in the term livestock.

While allied industries is not specifically defined, the term is understood within the context of the definition of livestock and poultry to include such animal products and by-products that are being produced, processed, preserved, and marketed for human consumption. The principle of ejusdem generis states that where a general word or phrase follows an enumeration of particular and specific words of the same class, the general word or phrase is to be construed to include – or to be restricted to – things akin to or resembling, or of the same kind or class as, those specifically mentioned.

Clearly, these products cannot be considered as veterinary drugs.

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19 Section 18, Book IV, Title IV, Chapter 4, E.O. No. 292
21 Section 2, R.A. No. 1556
22 Section 4, DA Administrative Order No. 05, series of 2019 (Guidelines on the Local Transport/ Shipment of Animals, Animal Products and By-Products, 03 September 2019)
23 Section 2 (23), Article II, BAI Administrative Order No. 35, series of 1975 (Rules and Regulations Governing the Manufacture, Importation, Labelling, Advertising, Distribution and Sale of Livestock and Poultry Feeds and Feeding Stuffs)
24 DA Administrative Order No. 05, series of 2019, SECTION 4 c. ANIMAL PRODUCTS – any material derived from the body of an animal. Examples are fat, flesh, meat, blood, milk, eggs, meat products (uncooked processed) and lesser known products, such as rennet.
25 Ibid, d. ANIMAL BY-PRODUCTS – are materials of animal origin that are unsuitable for human consumption. It may include but not limited to the following:
   - Animal feed – e.g. fishmeal, processed animal protein, pet food
   - Organic fertilizers and soil improvers – e.g. manure, guano
   - Other products – e.g. hides, horns, skins, bones, hooves, wool
E.O. No. 175 defines new veterinary drugs as those intended for use for animals including any drug intended for use in animal feeds but not including animal feeds within the contemplation of the implementing rules and regulations. These are drugs used to diagnose, cure, mitigate, treat, or prevent disease in animals, or intended to affect the structure of any function of their body, or for use as a component of any of these drugs used for animals and animal feeds.\(^3\)\(^6\)

Unlike food animals, products and by-products, veterinary drugs are discovered, developed, produced, and marketed by the pharmaceutical industry which is under the regulatory jurisdiction of the FDA to ensure that they are potent and safe to use in animals, whether food producing or not, to protect them and the consuming public. This is the primary reason for the establishment of the Center for Drug Regulation and Research under the FDA to regulate the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of drugs\(^3\)\(^7\) to ensure their safety, purity, and potency.

The FDA is the principal agency designated by law to carry out the constitutional mandate to maintain an effective food and drug regulatory system and to undertake appropriate health, manpower development, and research to cater to the country's health needs and problems.\(^3\)\(^6\) The regulatory authority of the FDA was further amplified under E.O. No. 175 when it included new veterinary drugs within its coverage. This is to ensure that the food, drug, and cosmetics in the market are pure and safe for human consumption.

In sum, the BAI's regulatory authority covers the animal industry including the production, processing, preservation, and marketing of animals, products and by-products for human food security as distinguished from the pharmaceutical/health industry that develop and produce veterinary drugs for animal health and human food safety which properly falls under the regulatory authority of the FDA.

Please be guided accordingly.

Very truly yours,

RAUL T. VASQUEZ
Undersecretary
Department's Officer-in-Charge (OIC)
(Per Department Order No. 247 dated 28 April 2023)

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\(^3\)\(^6\) Section 10 (f), Chapter V of R.A. No. 3720, as amended.

\(^3\)\(^7\) Section 6. Section 5 of Republic Act No. 3720, as amended, is hereby further amended and new subsections are added to read as follows:

"SEC. 5. The FDA shall have the following centers and offices:

"(a) The Centers shall be established per major product category that is regulated, namely:

"(1) Center for Drug Regulation and Research (to include veterinary medicine, vaccines and biologicals);

\(^3\)\(^8\) Section 12, Article XIII thereof