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Registration Guide for Feed Additives

Report Categories:
Exporter Guide
Trade Policy Monitoring

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Report Highlights:
This report provides information on the registration process for importing feed additives to Indonesia. The report is meant to provide a general overview of the requirements and procedures. Companies considering exporting feed additives to Indonesia should work closely with their importer and/or local agent as well the relevant ministries to ensure all legal requirements are met.

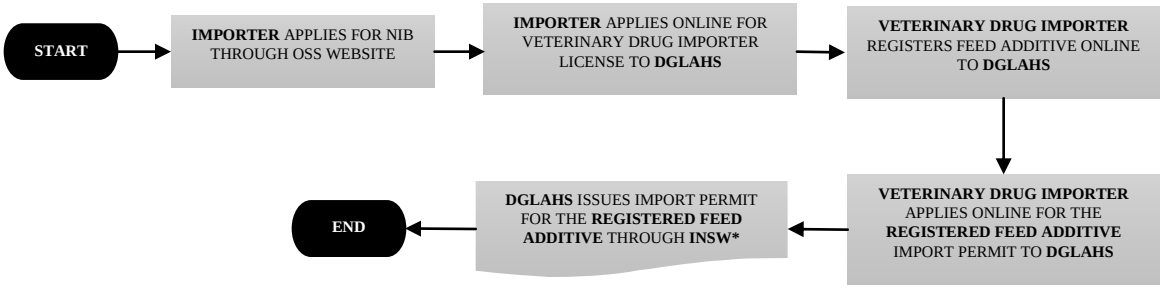
General Information:

Background

The Ministry of Agriculture (MOA) defines[1] a feed additive as a feed ingredient that does not contain nutrients, as opposed to a feed supplement, which is defined as a substance naturally contained in feed, the amount may be increased by providing supplementation to the feed. Feed additives are usually used for a specific purpose (growth promotion, therapy, etc.) and may contain medications. However, the same regulation also dictates that the use of feed additives containing active ingredients listed in its Attachment III (see Attachment 1 below) are not allowed for livestock products intended for human consumption.

Import Process

The Government of Indonesia requires importers to possess a Single Business Number (Nomor Induk Berusaha/NIB), obtainable online from the Coordinating Ministry of Economic Affairs[2] and a Veterinary Drug Business License from the Director General of Livestock and Animal Health Services (DGLAHS) before they can apply for a permit to import feed additives. In January 2019, MOA issued a new regulation on Agricultural Business Licensing[3] that requires businesses to obtain their Veterinary Drug Business License through Online Single Submission (OSS). However, the integration of Veterinary Drug Business Licensing section to the OSS is still in process. Currently, businesses must still use the existing DGLAHS online submission system, per previous regulation[4]. Separately, the feed additives must undergo an evaluation and the importer must register[5] the feed additives with DGLAHS before they can be imported.



*** INDONESIAN NATIONAL SINGLE WINDOW (INSW)** is a Ministry of Finance operated online portal that handles customs documents, licensing, and other documents relating to export, import and logistics activities

[1] Minister of Agriculture Regulation Number 14 Year 2017 regarding Veterinary Drug Classification
[2] Government Regulation Number 24 Year 2018 regarding Electronic Integrated Business Licensing Services
[3] Minister of Agriculture Regulation Number 5 Year 2019 regarding Business Licensing Procedures of the Agricultural Sector
[4] Minister of Agriculture Regulation Number 18 Year 2009 regarding Veterinary Drug Business License Requirements and Procedures
[5] Regulation of the Director General of Livestock and Animal Health Services Number 2 Year 2006 regarding The Permanent Procedure of Applying for Veterinary Drug Registration

Single Business Number (NIB)
Importers can apply for NIB at the OSS website (https://www.oss.go.id/oss/). NIB is a secured 13-digit number accompanied by an electronic signature obtainable by providing the businesses and its tax information into the OSS database. NIB also applies as Company Registration Certificate (Tanda Daftar Perusahaan/TDP), and Importer Identification Number (Angka Pengenal Importir/API), as well as providing importers with Customs Access Right. An English version of the guidelines on how to apply for NIB is available at https://oss.go.id/oss/portal/download/f/PedomanInggris.pdf.

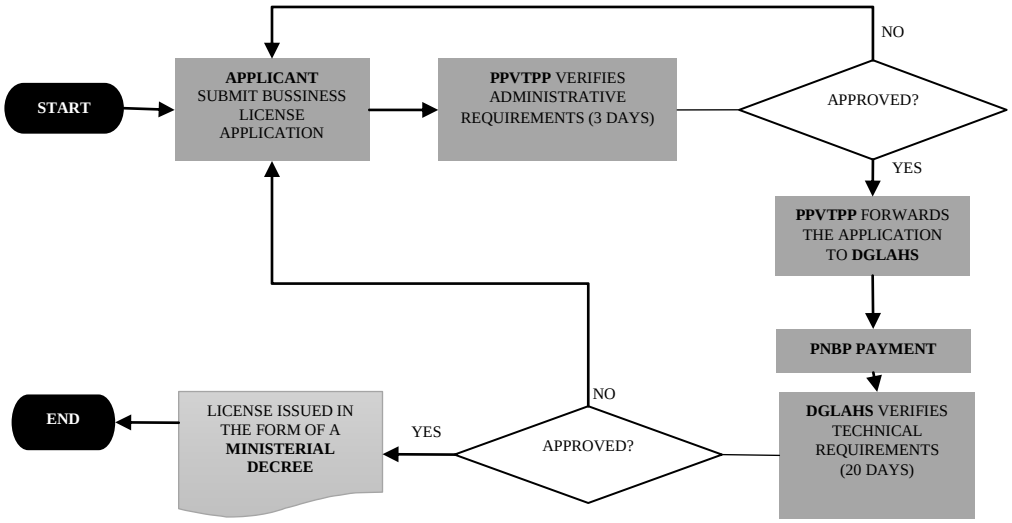
The NIB holder must proceed to obtain a specific business license from the technical ministry with responsibility for the commodity. In this case, importers of feed additives must proceed to apply for a Veterinary Drug Importer License to the Ministry of Agriculture.

Veterinary Drug Importer License
Importers may apply for this license through MOA's Electronic Agriculture Licensing System website (http://simpel.pertanian.go.id/) by choosing "Veterinary Drug Business" (*"Usaha Obat Hewan"*). The importer must comply with administrative and technical requirements[6] before the MOA Center of Plant Variety Protection and Agricultural Licensing (PPVTPP), and DGLAHS will consider the application.

Veterinary Drug Importer License Requirements	
Administrative	Technical
1. Tax Identification Number (NPWP); 2. Building Rights on Land (HGB); 3. Business Location License (SITU); 4. Obstruction Ordinance (Hinderordonnantie/HO); 5. Company Registration Certificate (TDP); 6. Trade Business License (SIUP); 7. Identification of the head of the business; 8. Import Identification Number (API); 9. Recommendation from the Heads of the Provincial and District/Municipal Services Office where the company headquarters is located, if the headquarters and the warehouse are in a same province; 10. Recommendation from the Heads of the Provincial and District/Municipal Services Office where the company warehouse is located, if the warehouse is in a different location from the headquarters; and 11. Recommendation from the local chapter or headquarters of the Indonesian Veterinary Drug Business Association (ASOHI).	1. Infrastructure/equipment to conduct their business; 2. Storage that can guarantee the quality of the veterinary drug stored; and 3. Full-time veterinarian or pharmacist that serves as the technical person in charge.

[6] MOA Regulation Number 18 Year 2009 Article 5 Paragraph 2 Number 2, and Article 6 Paragraph 2

VETERINARY DRUG IMPORTER LICENSE APPLICATION PROCESS



Upon receiving an application, PPVTPP has three working days to verify its administrative requirements and decide to approve, postpone, or reject it. PPVTPP will postpone an application if it is incomplete. The applicant has five working days to complete the application upon receiving the notification of postponement; otherwise, PPVTPP will assume that the applicant withdraws their application. If PPVTPP rejects the application, the applicant will receive a notification of rejection containing the reason(s) for rejection.

PPVTPP will forward approved applications to DGLAHS for technical verification. DGLAHS has 20 working days to approve or reject the application. If an application is approved, MOA will issue the Veterinary Drug Importer License in the form of Ministerial Decree.

Veterinary Drug Importer Licensing is subject to the payment of Non-Tax State Revenue (PNBP) fee[7], payable prior to DGLAHS' verification phase. The applicant (or their agent) will receive a pay order notification from DGLAHS which must in turn be presented to the Recommendation Services Unit (UPR) and Financial Office of DGLAHS in order to obtain a billing code for paying the fee at any bank within the Indonesian banking system.

Guidelines on obtaining a Veterinary Drug Importer License online are available at http://ap1.pertanian.go.id/obathewan/data/unduh/User Guide-Perizinan Usaha Obat Hewan v4.pdf

[7] Based on Government Regulation Number 35 Year 2016 regarding Types and Rates of Non-Tax State Revenue Applicable to the Ministry of Agriculture (see Attachment of the Regulation, page 92 number 3), the fee is IDR 2,000,000 per application.

Feed Additive Registration
Registered Veterinary Drug Importers may apply for feed additive registration at http://obathewan.ditjennak.pertanian.go.id. The registration process consists of several phases:

1. *Importer company information, documents submission, and National Veterinary Drug Assay Laboratory (BBPMSOH) certification.* The verification team (UPR, Operator, Section Head[8], and Deputy Director[9]) verifies all documents submitted and their approval will allow the applicant to submit feed additive preparation samples to BBPMSOH. Documents that must be attached[10] and uploaded for the feed additive registration are:

    a. Attachment A on veterinary drug composition;

    b. Attachment B on veterinary drug preparation manufacturing process;

    c. Attachment C on inspection of veterinary drug;

    d. Attachment D on veterinary drug ingredients inspection;

    e. Attachment E on inspection of stability;

    f. Attachment F on veterinary drug pharmacological potent;

    g. Attachment G on field clinical trial publication;

    h. Attachment H on the information on container and packaging;

    i. Attachment I on the information on container cover;

    j. Attachment J on the marking information;

    k. Attachment K on sample of the preparation and active ingredients standard; and

    l. Attachment L on other information of the manufacturer and the imported products.

    Additional documents required for importation of feed additives are:
    1. Certificate of Origin, authorized by the representative of the Republic of Indonesia in the country of certificate issuance;

    2. Certificate of Registration, authorized by the representative of the Republic of Indonesia in the country of certificate issuance;

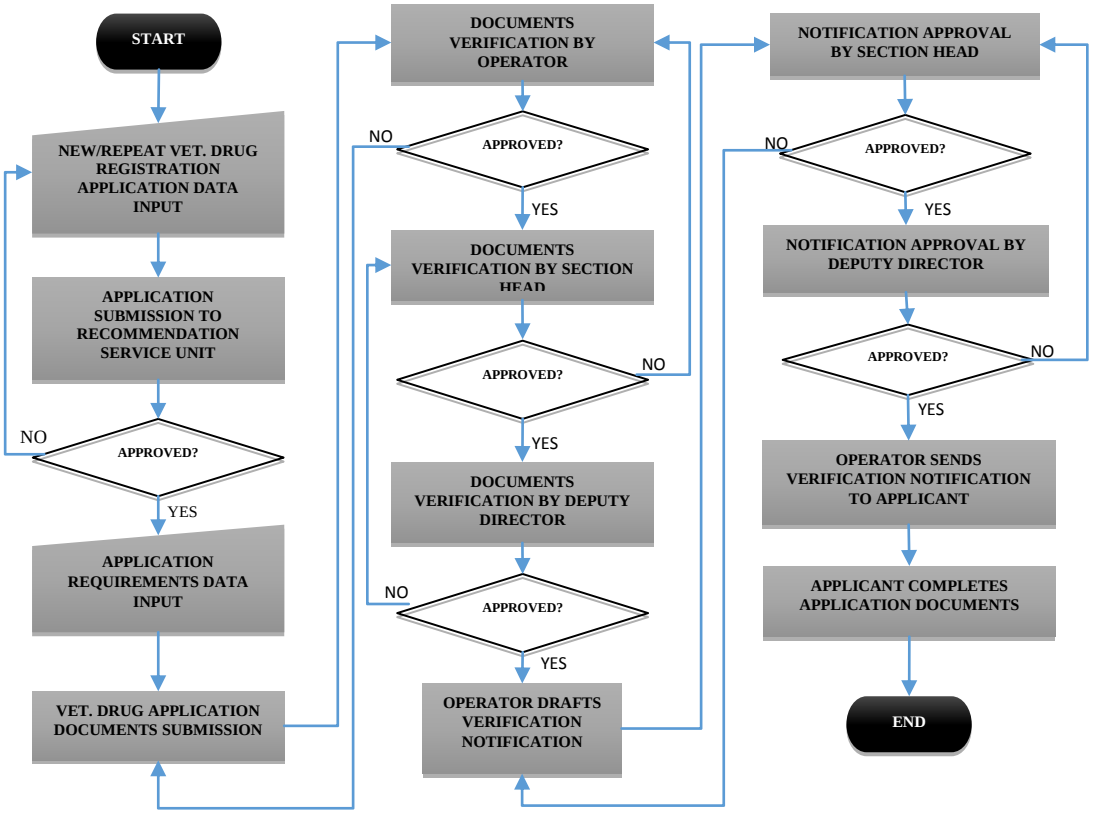
    3. Certificate of Free Sale, authorized by the representative of the Republic of Indonesia in the country of certificate issuance;

[8] Veterinary Drug Registration Section Head of the Veterinary Drug Control Sub Directorate of the Directorate of Animal Health (DAH), DGLAHS
[9] Deputy Director for Veterinary Drug Control, DAH, DGLAHS
[10] Based on the Decree of the Director General of Livestock Services Number 55 Year 2001 regarding Veterinary Drug Registration Application Form

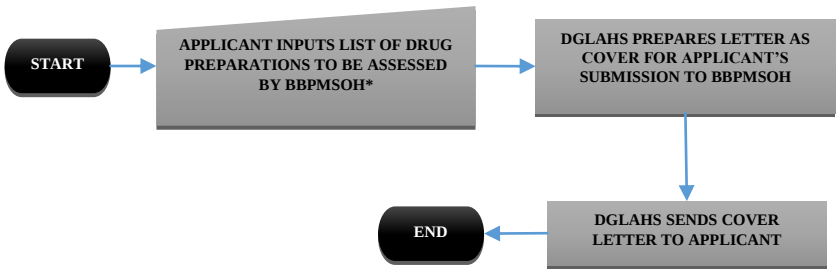
4. Certificate of Good Manufacturing Process (GMP), authorized by the representative of the Republic of Indonesia in the country of certificate issuance;
5. Letter of appointment from the manufacturer in the country of origin or its representative as the registration holder; and
6. Photo of the manufacturing plant.

Upon approval of the submitted information and uploaded documents, the verification team will notify the applicant through the online system to submit more information on feed additive preparation, including where to collect the preparation sample for BBPMSOH assessment. DGLAHS will provide a cover letter to the list of veterinary drug preparations the applicant will send to BBPMSOH. Upon completion, BBPMSOH will issue an Assessment Result Certificate, which the applicant must upload to the online system in order to have the registration process proceed to the next phase. The duration of the preparation sample assessment is 35 working days for feed additives having two active ingredients. An additional assessment time of 35 days is needed for every one active ingredient added to the combination.

VETERINARY DRUGS REGISTRATION APPLICATION & REQUIREMENTS FLOW CHART

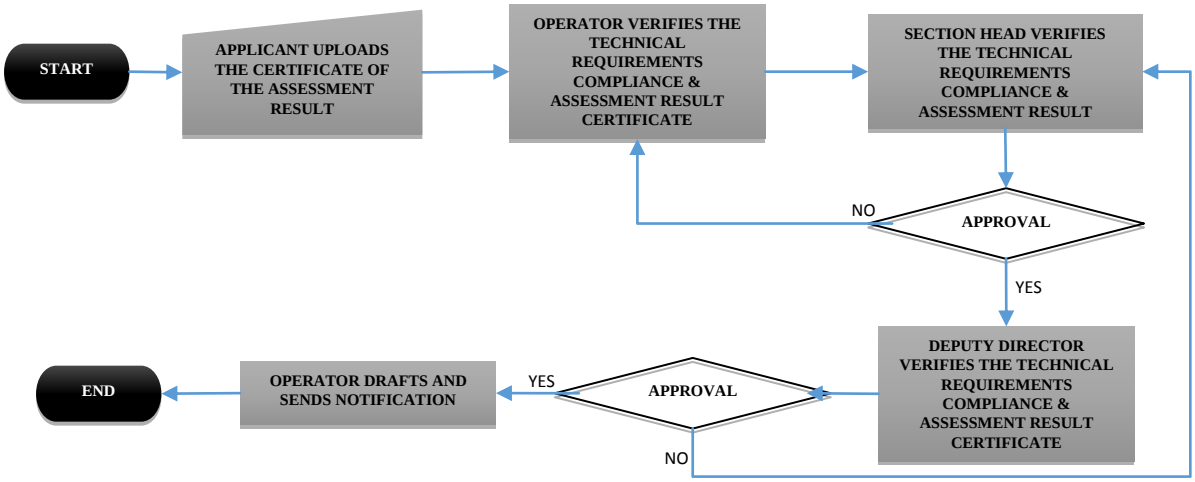


LIST OF VETERINARY DRUG PREPARATIONS INPUT FOR ASSESSMENT BY BBPMSOH



* BBPMSOH = National Veterinary Drug Assay Laboratory, an institution under the DGLAHS

ASSESSMENT RESULT CERTIFICATE UPLOAD FLOW CHART



2. *Assessment by the Veterinary Drug Registration Committee (PPOH) or the Veterinary Drug Commission (KOH).* Assessment of feed additives containing active ingredients, having the same combination, formulation, or indication with other drugs that have been approved previously by PPOH or KOH ("me too" drugs) will be done at PPOH level. While assessment of feed additives

considered as "new", in accordance to the legislation,[11] will be done at KOH level. A feed additive preparation is considered as "new" if it:

a. contains a new active ingredient, or
b. contains existing active ingredients, but with new indication, or
c. contains a new combination of the existing active ingredients, or
d. is a new formulation including additional substance

In order to obtain sufficient information, PPOH and KOH may consult the feed additive manufacturer or importer for more information. Feed additive manufacturer/importer must provide the requested information within 40 working days, otherwise PPOH or KOH will assume that the applicant withdraws their application. This phase, excluding the time needed to obtain additional information, will take 50 working days for the assessment by PPOH, and 120 working days for the assessment by KOH.

3. *Establishment of Veterinary Drug Registration Number*. The Director General of Livestock and Animal Health Services will use the result of PPOH and/or KOH assessments in granting the Veterinary Drug Registration Number in the form of a Decree of the Director General of Livestock Services. DGLAHS will deliver the Decree after receiving the payment proof of Non-Tax State Revenue (PNBP) fee,[12] to which the registration of feed additive is subject. The Veterinary Drug Registration Number will valid for 10 years from the date of issuance.

Guidelines on obtaining Veterinary Drug Registration Number online is available at http://obathewan.ditjennak.pertanian.go.id/site/downloadfile?name=08.+Manual+Aplikasi+OH_Pelaku+Usaha_ver1.0.pdf.

Feed Additive Import Permit

A Registered Veterinary Drug Importer applies for this license through MOA's Electronic Agriculture Licensing System website (http://simpel.pertanian.go.id/) by choosing "Veterinary Drug Import" (*"Pemasukan Obat Hewan"*). The Importer must obtain login username and password by email request to yanrekditjenpkh@pertanian.go.id.

The process of obtaining Feed Additive Import Permit follows the provisions of the Regulation of the Minister of Agriculture Number 5 Year 2019, which requires the applicant to:

1. Submit permit application through the above-mentioned OSS website; and
2. Submit a Commitment to comply with the requirements to obtain veterinary drug import permit.

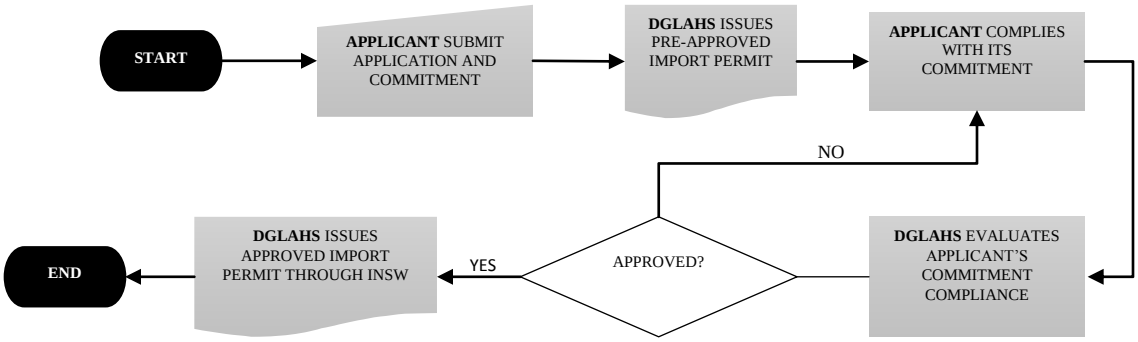
[11] Based on the Minister of Agriculture Decree Number 695 Year 1996

[12] Based on Government Regulation Number 35 Year 2016 regarding Types and Rates of Non-Tax State Revenue Applicable to the Ministry of Agriculture (see Attachment of the Regulation, page 89 point D.2.), the fee is IDR 5,000,000 per feed additive preparation.

According to the provisions of Article 60 of the Regulation of the Minister of Agriculture Number 5 Year 2019, the importer must commit, as referred to point number 2 above, to submit the following documents as the requirements to obtain the import permit:

1. Ministerial Decree regarding the Establishment of the Registered Veterinary Drug Importer status;
2. Application specification sheet;
3. Invoice/Proforma invoice/purchase order;
4. Latest and valid Certificate of Analysis;
5. Certificate of Origin, in the country of origin is different from the producing country;
6. Decree of the Director General of Livestock Services regarding the Establishment of the Veterinary Drug (in this case the Feed Additive) Registration Number;
7. Letter of Approval from the holder of the Veterinary Drug Registration Number, if the importation is performed not by the holder of the Veterinary Drug Registration Number;
8. Veterinary Health Certificate for importation of biological preparation;

DGLAHS will issue the Veterinary Drug Import Permit pre-approval based on the above commitment. Applicant must comply with and upload the above commitment through the OSS website within 30 working days from the date of the issuance of the pre-approval. DGLAHS will then evaluate all documents submitted, and within 30 working days at the latest from the date when the commitment is submitted, notify the result of the evaluation through the OSS website.



Based on the evaluation, DGLAHS as the final approver will declare if the applicant has complied with its commitment and issue the veterinary drug import permit through the Ministry of Finance's Indonesia National Single Window (INSW) website. The permit's validity period shall be 3 months, and valid for one shipment. The permit is subject to Non-Tax State Revenue (PNBP)[13] payment applicable to the Ministry of Agriculture which applicant will have to pay upon the publication of the veterinary drug

[13] Based on Government Regulation Number 35 Year 2016 regarding Types and Rates of Non-Tax State Revenue Applicable to the Ministry of Agriculture (see Attachment of the Regulation, page 91 point F.e.2)), the fee is **IDR 200,000** per import permit document.

registration number[14].

Attachment 1

ATTACHMENT III
REGULATION OF THE MINISTER OF AGRICULTURE
OF THE REPUBLIC OF INDONESIA
NUMBER 14/PERMENTAN/PK.350/5/2017
REGARDING VETERINARY DRUG CLASSIFICATION

LIST OF VETERINARY DRUG PROHIBITED TO BE USED FOR LIVESTOCK WHICH PRODUCTS ARE FOR HUMAN CONSUMPTION

No.	VETERINARY DRUG DESCRIPTION	REMARK
A.	VETERINARY DRUG GROUP PROHIBITED TO BE MIXED INTO FEED AS FEED ADDITIVE FOR PRODUCTION LIVESTOCK CONSUMPTION	
	Antibiotics	
B.	CERTAIN VETERINARY HORMONES GROUP PROHIBITED TO BE USED FOR PRODUCTION LIVESTOCK	
	Synthetic hormones	
C.	CERTAIN VETERINARY DRUG GROUP PROHIBITED TO BE USED	
	a. Prohibited to be mixed as Feed Additive	

[14] The payment mechanism is described in the point number III.C.d.(a).4. of the Attachment of the Regulation of the Director General of Livestock Services Number 02/Kpts/LB.450/F/03/06 regarding the Permanent Procedures of Veterinary Drugs Registration.

	1. Argentum proteinate (colloidal silver) 2. Lysergic Acid Diethylamide (LSD) 3. Dimetridazole 4. Dipyrone 5. Phenylbutazone 6. Dyes: Gentian Violet, Rhodamin, Methyl Yellow, Methyl Red, Malachite Green, Auramine, Metanil Yellow, Methyl Violet, Ponceau 3R. 7. Beta 1-adrenergic agonist group 8. Beta 2-adrenergic agonist group 9. Pesticide group, with the exception of cyromazine 10. Ipronidazole 11. Carbadox 12. Carbon tetrachloride 13. Roxarsone 14. Thalidomide b. Prohibited for oral, parenteral and topical use: 1. Amphetamine 2. Dihydrostreptomycin (DHS) 3. Chloramphenicol 4. Nitrofuran 5. Phenylbutazone 6. Beta 1-adrenergic agonist 7. Beta 2-adrenergic agonist 8. Carbadox 9. Carbon tetrachloride 10. Olaquindox 11. Roxarsone 12. Thalidomide 13. Antibiotics mixed with vitamin, mineral, amino acid, and veterinary natural remedies 14. Veterinary natural remedies mixed with synthetic veterinary Drug.	

MINISTER OF AGRICULTURE

signed

AMRAN SULAIMAN