FDA CIRCULAR
No. _____

SUBJECT: **Interim Guidelines for the Issuance of License to Operate (LTO) and Certificate of Product Registration (CPR) for Non-Medicated Veterinary Products/Cosmetics and Veterinary Medical Devices**

I. BACKGROUND

In accordance with the provisions of the Republic Act (RA) No. 3720, Subject: *Food, Drug, and Cosmetic Act*, as amended by Executive Order No. 175 and RA No. 9711, subject: *Food and Drug Administration Act of 2009*, the FDA is mandated to cover the regulation of manufacture, distribution, sale, offer for sale, and other regulated activities and monitoring of veterinary drugs and products, veterinary biological products, device and establishments.

Previously, several issuances including the 1991 Memorandum of Agreement (MOA) and the Joint Administrative Order (JAO) No. 2013-0026 between the Department of Health – Food and Drug Administration (DOH - FDA) and Department of Agriculture – Bureau of Animal Industry (DA-BAI), allowed a shared arrangement in the regulation of veterinary drugs and products and devices between the two (2) agencies.

Following the expiration of the aforecited policies, and to ensure the continuous delivery of service, the Center for Drug Regulation and Research (CDRR) is tasked to facilitate the process for the approval of these health products and hereby provide the interim guidelines for the issuance of authorizations for veterinary products/cosmetics (non-medicated) and veterinary medical devices.

II. OBJECTIVES

This Circular aims to provide the interim guidelines for the licensing, registration and post-market surveillance (PMS), and issuance of other certifications for non-medicated veterinary products/cosmetics, medical device and establishments.

III. SCOPE

This issuance shall apply to establishments engaged in the manufacture, trade, distribution, importation, and/or exportation of non-medicated veterinary products/cosmetics and veterinary medical devices in the Philippines.

For the purposes of this Circular, Non-Medicated Veterinary Product/Cosmetics and Veterinary Device shall refer to:

Non-Medicated Veterinary Product/Cosmetics - any substance or preparation intended to be placed in contact with various external parts of the animal body or with teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition. This excludes products applied to eyes or the teats of animals producing milk.

Veterinary Medical Device - an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part or accessory intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment or prevention of disease, in animals or intended to affect the structure or any function of the body of animals and which does not achieve any of its principal intended purposes through chemical action within or on the body of other animals and not dependent upon being metabolized for the achievement of any of its principal intended purposes.

IV. GENERAL GUIDELINES

A. Licensing Requirement

Establishments intending to manufacture, trade, distribute, import, and/or export non-medicated veterinary products and veterinary medical devices shall secure a License to Operate (LTO) with the Center for Drug Regulation and Research (CDRR) of the FDA through the procedure outlined in Section V.1. Correspondingly, establishments shall be classified as Drug Establishments (Manufacturer, Trader, Distributor, as applicable), in the interim.

B. Product Authorization Requirement

Non-medicated veterinary products/cosmetics and veterinary medical devices intended to be placed in the Philippines must be registered by a licensed establishment with FDA-CDRR, following the procedure outlined in Section V.2. Correspondingly, products shall be classified as Pharmaceutical Products or Drugs, in the interim.

C. Labeling

Such products must comply with the minimum labeling requirements provided in **Annex B** for non-medicated veterinary products/cosmetics, and **Annex C** for veterinary medical devices.

D. Post-Approval Changes

Should there be any amendment or post-approval change (PAC) either in the activity conducted by the establishments as reflected in the LTO or in the product as reflected in the corresponding CPR, the establishments shall apply for variation or notification with the FDA as may be applicable.

E. Continuous Compliance

The Market Authorization Holder (MAH) shall ensure continuous compliance with the safety, efficacy, and quality standards instituted by the FDA. Correspondingly, the MAH must adhere to the terms and conditions that are specified in all authorization granted to them.

F. Cancellation of an Authorization

Should the applicant or MAH commit violations to the FDA rules, regulations, and standards, applications may be disapproved and/or authorizations may be suspended, revoked, or cancelled. In such cases, a notice of disapproval of the application or notice of suspension, revocation, or cancellation shall clearly state the grounds for such.

G. Non-Registrable Products

The conditions for product classification of veterinary products and those that **do not** require registration are listed in **Annex D**.

The License to Operate (LTO) of the establishment shall be provided in lieu of the Certificate of Exemption at the point of entry and/or as part of bidding requirements.

H. Previously-issued Authorizations

All provisions under FDA Memorandum Circular No. 2021-001 shall remain in effect. As such, existing and valid authorizations granted by DA-BAI to establishments and products within the scope of this Circular shall be honored by FDA; while authorizations expiring from March to July 2021 shall be given an automatic validity extension of six (6) months from the date of expiry.

V. SPECIFIC GUIDELINES

1. Application for a License to Operate (LTO)

1.1 Filing of Applications

1.1.1 Applications for the issuance of LTO shall be submitted through the FDA eServices System.

1.1.2 Applicant establishments shall follow the licensing procedure as prescribed in the following issuances:

1.1.2.1 Administrative Order No. 2020-0017, subject: *Revised Guidelines in the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003;* and

1.1.2.2 Administrative Order No. 2020-030, subject: *Guidelines in the Use of eServices Portal System for License to Operate Application of Drug Distributors, Drug Traders, Drugstores, Retail Outlets for Non-Prescription Drugs (RONPD), Clinical Research Organizations (CRO) and Sponsors.*

1.1.3 All applications shall be deemed filed upon payment of required fees and charges.

1.2 Documentary Requirements for Issuance of LTO

The following are the documentary requirements for the issuance of LTO, applied as initial, and for renewal:

1.2.1 Accomplished Application Form and Declaration and Oath of Undertaking (eservices.fda.gov.ph).
1.2.2 Proof of Business Name Registration shall be submitted in any of the following:
1.2.2.1 For Single Proprietorship – copy of Certificates of Business Registration issued by the Department of Trade and Industry (DTI);
1.2.2.2 For Corporation, partnership and other judicial person – Certificate of Registration issued by the Securities and Exchange Commission (SEC), and Articles of Incorporation; or
1.2.2.3 For Cooperative – Certificate of Registration issued by the Cooperative Development Authority (CDA), and Articles of Cooperation
1.2.3 Site Master File (SMF)
1.2.4 Proof of Payment based on the latest FDA issuance.

Establishments applying for variation shall follow the List of Requirement for Specific Variation in the LTO as detailed in Annex C of AO No. 2020-0017, Subject: *Revised Guidelines in the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003.*

1.3 Evaluation

The evaluation of all applications for LTO shall be based on satisfactory compliance to the applicable requirements or appropriate standards.

1.4 Inspection

1.4.1 Manufacturers applying for LTO shall undergo Field Regulation Operations Office (FROO) inspection prior to the issuance of initial LTO. Other covered establishments shall be inspected by FDA at any time within the validity of its license as part of its post-licensing inspection and post-marketing surveillance activities.
1.4.2 During inspection, the establishment will be required to present the following documents, as may be applicable:
1.4.2.1 Standard Operating Procedure (SOPs)
1.4.2.2 Quality Assurance / Quality Control Documents
1.4.2.3 Documents relating to the manufacture of the product
1.4.2.4 Documents relating to the distribution of the product
1.4.2.5 Contract Agreements, if applicable

1.5 Decision on Application

1.5.1 The appropriate authorization shall be issued to the applicant establishment which satisfactorily complied with all applicable requirements and standards

1.5.2 The application shall be disapproved if upon evaluation, it was found that the applicant establishment has failed to satisfactorily meet the applicable requirements and standards.

1.5.3 Applications with incomplete requirements shall automatically be disapproved and requests for reconsideration shall not be entertained.

1.5.4 The disapproval of an application is without prejudice to re-application. However, disapproval of application shall mean outright forfeiture of payment.

2. Application for a Certificate of Product Registration (CPR)

2.1 Filing of Application

The guidelines on the procedures and schedules of applications indicated in the FDA Circular No. 2020-026, subject: *Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the food and Drug Administration (FDA)* shall be followed. Only the accepted pre-assessed application will be processed.

2.2 Guidelines for Product Registration

2.2.1 The requirements for registration of Non-medicated Veterinary Products/ Cosmetics and Veterinary Medical Devices are specified in **Annex A** and **B**.

2.2.2 An application for CPR, whether initial, renewal or variation is deemed filed after acceptance of the pre-assessed applications including payment of required fees and charges.

2.2.3 Action on registration application shall be based on the complete set of specifications of the product proposed to appear in the label, i.e. formulation, form, indications, and manufacturer. Any change in the mentioned specifications shall require a new registration.

2.2.4 A violation with any of the terms and conditions of the CPR shall likewise result in the suspension, revocation or cancellation of the CPR or disapproval of the application for renewal, after due process.

2.2.5 Post-Approval Changes (PAC)/ Variation of the product and devices shall be applied following the existing requirements for Post-Approval Changes FDA Circular No. 2014-008, subject: *Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products*.

3. Validity of Authorizations

The LTO and CPR shall be issued and shall have a validity of three (3) and five (5) years from the date of issuance respectively.

4. Post-Market Surveillance of Non-Medicated Veterinary Products/Cosmetics and Veterinary Medical Devices

Non-Medicated Veterinary Products/Cosmetics and Veterinary Medical Devices shall be subject to post-marketing surveillance activities of FDA. Applicable regulatory tools shall be implemented to non-compliant and violative products/devices.

5. Fees and Charges

Applications shall be charged with the fees pursuant to the schedule of fees stated in the AO No. 50 s. 2001, or its future amendments.

VI. EFFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and upon acknowledgement of receipt of a copy hereof by the UP Office of the National Administrative Register until the issuance of a formal designation on the Centers to handle such products.

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Keywords	Non-Medicated Veterinary Products/Cosmetics, Veterinary Medical Devices, eServices, License to Operate
Related Issuances, laws, directives from other government agencies	JAO No. 2013-0026, AO No. 2020-0017, AO No. 2020-030, FDA MC No. 2021-001, FDA FC No. 2020-001,

ANNEX A

REQUIREMENTS FOR PRODUCT REGISTRATION

I. NON-MEDICATED VETERINARY PRODUCTS/COSMETICS

	REQUIREMENTS	TYPE OF APPLICATION	
		INITIAL	RENEWAL
1	Notarized Integrated Application Form	√	√
2	Valid agreements between the manufacturer, trader, importer, distributor, where applicable	√	
3	Copy of BAI issued Certificate of Product Registration (CPR)	√	√
4	Unit dose and batch formulation	√	
5	Technical Specifications of all Raw Materials	√	
6	Certificate of Analysis of Active Raw Material(s)	√	
7	Technical Specifications of Finished Product	√	√
8	Certificate of Analysis (CA) of Finished Product	√	√
9	Manufacturing Procedure, Production, Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)	√	
10	Assay and other test procedures including identity, purity tests, with data analysis where applicable	√	√
11	Stability Studies	√	√
12	Labeling Materials (facsimile labels)	√	√
13	Representative Samples (as requested)	√	√
14	For Imported products: a. Certificate of Pharmaceutical Product (CPP) b. Foreign Good Manufacturing Practice (GMP) Clearance	√	√
15	Valid LTO (Importer/ Manufacturer/ Distributor/ Trader)	√	√

II. VETERINARY MEDICAL DEVICE - *IN-VITRO* DIAGNOSTIC DEVICE (IVD)

REQUIREMENTS	TYPE OF APPLICATION	
	INITIAL	RENEWAL
1. Table of Contents (with page number)	√	√
2. Notarized Application Form from Distributor (Importer/Exporter/Wholesaler)/Local Manufacturer/ Trader	√	√
3. Certificate of Brand Name Clearance (for branded products, if applicable)	√	
4. Valid License to Operate (LTO) as Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader	√	√
5. Valid Government Certificate of Clearance and Free Sale/Registration approval of the Product from the country of origin issued by the Health Authority and duly authenticated by the territorial Philippine Consulate for Imported Product	√	
6. Valid Government Certificate attesting to the status of the manufacturer, competency and reliability of the personnel and facilities or valid ISO Certification. For imported products, certificate must be and duly authenticated by the territorial Philippine Consulate	√	√
7. Copy of latest Certificate of Product Registration	N/A	√
8. Certificate of Foreign Agency Agreement between the manufacturer and trader/distributor/importer regarding the product involved duly authenticated by the territorial Philippine Consulate	√	√
9. Intended use and directions for use	√	
10. List of all raw materials used as components of the reagents/test kit	√	
11. Technical specifications and physical description of the Finished Product	√	
12. Process-control/Test Procedure and expected performance specification including the sensitivity and specificity	√	
13. Brief description of the methods used in the facility and the controls in the manufacture, processing, packaging of the IVD and the process flowchart showing an overview of production	√	
14. Risk analysis with control measures	√	
15. A. For INITIAL: Stability test data and results describing the shelf life, in-use stability, and the shipping stability studies to justify claimed shelf life. The testing should be performed on at least three (3) different product lots manufactured under conditions that are essentially equivalent to routine production conditions. B. For RENEWAL: Stability test data and results describing the shelf life. The testing should be performed on at least three (3) different product lots manufactured under **REAL TIME CONDITION**.	√	√
16. A. For INITIAL: Labeling materials to be used for the product: Immediate label, secondary packaging, box label and package insert/brochure. B. For renewal, submit clear and readable commercial product label specimen of all labeling materials (outer, immediate, package insert)	√	√
17. For the diagnostic/pregnancy kits, 15 samples of the same lot with at least nine (9) months expiration date.	√	√
18. Evidence of registration fee/payment (charge slip/official receipt)	√	√

ANNEX B

MINIMUM LABELLING REQUIREMENTS FOR NON-MEDICATED VETERINARY PRODUCTS/COSMETICS

The following particulars shall appear on the outer packaging of the products, or where there is no outer packaging, on the immediate packaging of the products:

i. Product Name;
ii. Full ingredient / Content listing expressed in metric system;
iii. Pack Size / Net Content;
iv. The ingredients / content must be declared in descending order of weight at the time they are added;
v. Instructions on the use of the product;
vi. Storage Condition;
vii. Name and address of the Market Authorization Holder;
viii. Name and Address of the Manufacturer responsible for placing the product in the local market;
ix. Registration Number;
x. Batch and Lot Number;
xi. Expiration Date and Date of Manufacture of the product in clear terms (e.g. month/year). The date shall be clearly expressed and shall consist either of the month and year, or the day, month, and year in that order. The date of minimum durability shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with article. It should be preceded by the words "expiry date" or "best before". If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability;
xii. Special precautions to be observed in use such as "Conditions of use and warnings which must be printed which must appear on the label as well as any special precautionary information on the products. There must be a statement on the product label signaling the presence of ingredients of animal origin in which the exact animal must be declared;
xiii. In cases where the size, shape, or nature of the container or package does not permit the particulars laid down in paragraphs 1 (a) – (i) to be displayed, the use of leaflets, pamphlets, hang tags, display panel, shrink wrap, etc. shall be allowed. However, the following particulars at least shall appear on small immediate packaging: a) The name of the product; and b) The manufacturer's batch number; and
xiv. The following are the acceptable cosmetic messages for non-medicated veterinary product/cosmetics:

Product Types	Acceptable Claims
Skin, coat, hair and fur products	Cleans, washes or conditions skin, coat, hair or fur Removes loose dandruff (flakes) Adds body to hair or fur; helps make hair or fur look fuller Revitalizes coat appearance; adds shine to coat; promotes lustre
Deodorants, colognes and perfumes (such as essential oils)	Fragrant, anti-odorant (deodorant), fights bad odor, makes animal smell fresh or nice, Absorbent, helps keep animal dry.
Emollient skin products (Moisturizer)	Moisturizes, hydrates, lubricates, or softens (dry) skin Revitalizes skin appearance, smooths or re-textures skin Protects dry skin from exposure to elements or wind, prevents or protects against drying effects of the sun, moisturizes sun-damaged skin.
Hoof and Pad Products	Softens hooves or pads Protects hooves or pads from drying.
Dental Products	Teeth-cleaning products that work by their physical cleaning action only (not by any biochemical or antimicrobial effect) Breath-freshening products that mask odors and freshen the animal's breath.
Teeth cleaning products	Cleans; whitens; brightens; removes stains or polishes teeth Helps maintain normal healthy teeth and gums Fluoride protects against tooth decay For deodorizer mouth rinse or spray: helps eliminate or fights bad breath or odor

ANNEX C

LABELLING REQUIREMENTS FOR VETERINARY MEDICAL DEVICE

I. Veterinary Medical Devices

The following specific content of labeling that shall appear in the packaging for medical devices:

1. Product name, trade name or brand name to permit the user to identify the medical device.
2. Name, address and contact details (e.g. phone number, and website address to obtain technical assistance) of the product owner.
3. Registration number issued by the FDA-CDRR on all levels of packaging.
4. Name and address of the importer and/or distributor. It is mandatory to all levels of packaging unless the sterility and self-life will be compromised.
5. Sufficient details for the user to identify the medical device and, where these are not obvious, its intended purpose, user and patient population of the medical device; also, where relevant, the contents of any packaging.
6. Batch code, lot number or the serial number, if applicable.
7. Expiration date expressed at least as year and month (e.g. 2021-NOV), if applicable.
8. Special storage/container, handling conditions and/or storage conditions.
9. Manufacturing date expressed at least as year and month.
10. The information needed to verify whether the medical device is properly installed and can operate correctly and safely, including details of the nature, and frequency of preventive and regular maintenance, where relevant any quality control, replacement of consumable components, and calibration needed to ensure that the medical device operates properly and safely during its intended life, if applicable
11. The performance intended by the product owner and, where relevant, any undesirable side effects.
12. Details of any further treatment or handling needed before the medical device can be used (e.g. sterilization, final assembly, calibration, preparation of reagents and/ or control materials, etc.) where relevant.
13. Identification for “sterile medical device” and where appropriate, the sterilization method (e.g. sterilized using aseptic processing techniques; sterilized using ethylene oxide; sterilized using irradiation and/or sterilized using steam or dry heat); the information about what to do if the sterile packaging is damaged; and instructions for re-sterilization, if applicable.
14. Identification for “single-use only” medical device as specified by the product owner.
15. Identification for “reusable medical device”, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses.
16. The requirements for sterilization of a medical device before it used and instructions for cleaning and sterilization process.
17. Indication for “refurbished” medical device and the date of refurbishment shall be indicated.
18. Identification for a “custom-made” medical device and a statement that it shall be used by a qualified practitioner.
19. If the medical device is intended for “clinical investigation” or, for IVD medical devices, “performance evaluation only”, an indication of that situation.

20. It shall be labeled if the medical device is intended for "research use only" and for "presentation or demonstration purposes only": not use on humans.
21. If the medical device is intended for research use only, it must be labelled as "research use only".
22. Particular risks in connection with implantation of an "implantable" medical device. .
23. IVD medical device shall be labeled as "In-vitro diagnostic" or "IVD".

II. *In- vitro* Diagnostic Veterinary Medical Devices

In addition to the information required for medical devices, directions/ instructions for the proper use of IVD medical device shall contain the following:

a. Intended purpose, with the following information:

   i. Type of analyte or measure and of the assay.
   ii. Whether the test is quantitative or qualitative.
   iii. Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic, monitoring.
   iv. Disease or condition that the test is intended for.
   v. Type of specimen to be used e.g. serum, plasma etc. The intended users (e.g. self-testing by lay person, near patient by trained personnel or professionals).
   vi. Assay type e.g. immunoassay, chemistry, cytochemistry, image analysis, immunohistochemistry.
   vii. The specific name of the instrument required for the assay, if any.
   viii. For instruments, the intended purpose should also include the modes of operation for instruments e.g., random access, batch, stat, open tube, closed tube, automatic, manual.

b. Test principle.
c. Specimen type.
d. Conditions for collection, handling, storage and preparation of the specimen.
e. Reagent description and any limitation (e.g. use with a dedicated instrument only).
f. The metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order.
g. Assay procedure including calculations and interpretation of results.
h. Information on interfering substances that may affect the performance of the assay.
i. Performance characteristics (summarized analytical and diagnostic sensitivity, specificity, reproducibility, etc.)
j. Reference intervals.
k. Study design (population studies, N, type of sample, matrix, dilution, target concentrations, etc.).

ANNEX D

CONDITIONS FOR VETERINARY PRODUCT CLASSIFICATION

I. Non-Medicated Veterinary Products/Cosmetics

1. Products that are applied to normal healthy, intact (unbroken) skin or hair or fur of animals for the purpose of altering their physical appearance are classified as non-medicated veterinary product/cosmetic and **require** registration, as long as the products do not:

    a. Contain antiseptics, antimicrobials, antiparasitic, antibiotics or other active constituents
    b. Make any health, production or performance claim.

2. To be considered as such, the products must only be applied topically to an animal and they must not make any representation or claim on their label or other promotional material.

    Examples of cosmetic products excluded from registration include:

    a. Non-medicated shampoos and coat conditioners to help clean, condition or shine an animal's skin, coat or fur.
    b. Non-medicated deodorants or perfumes to help mask odors or make animals smell fresh.
    c. Non-medicated emollients to help moisturize or soften an animal's skin, hooves or pads.
    d. Non-medicated toothpaste to help clean teeth and gums.
    e. Non-medicated ear cleaners to help clean and deodorize dirty ears by softening and removing the build-up of wax and dirt. These ear cleaners must not contain any antimicrobial or anti-inflammatory ingredient such as malic acid, lactic acid, acetic acid or salicylic acid, any disodium edetate, or any other approved active constituent or synergist.
    f. Essential oils when only represented as being suitable as a fragrance and when the directions for use result in essential oils making up 1% or less of the product being applied to an animal's skin.

3. If any recognized ingredient in the product is known to have a therapeutic effect, whether or not it is shown on the label, the product will fall under the definition of a veterinary drug. For example, essential oil products, which are known to have some antiseptic and insect repellent effects, require registration when their directions for use result in essential oils making up more than 1% of the product being applied to an animal's skin, regardless of the product representations.

4. Non-medicated veterinary product/cosmetics that do not comply with the above cited requirements, or any product represented as being suitable for or used for modifying the health, production, performance or behavior of an animal, **require** registration. For

example, medicated shampoos, conditioners, emollients and essential oils, when represented or used as an antimicrobial, antiseptic or insect repellent product, will require registration.

II. Veterinary Medical Devices, Equipment and Physical Barrier Products

1. Veterinary devices and equipment that are used to assist in veterinary medical or surgical procedures, are chemically inert and act by physical rather than biochemical means, and make no claim other than that arising from their physical action, generally **do not** require registration. The following are examples:

    a. Surgical instruments and equipment used to help perform surgical procedures that treat or prevent diseases or conditions (such as wounds);
    b. Non-medicated bandages used to support the musculoskeletal system or to prevent or treat injuries (such as wounds);
    c. Hoof repair resin or putty used for repairing defects in horses' hooves; and
    d. Adhesive glue used for repairing wounds.

2. Equipment that produces or emits sound, light or electromagnetic radiation. However, if the equipment produces a substance that has a biochemical action, for example an antiseptic teat dip, the equipment would need to be approved as part of the approval for the substance it produces.

3. Physical barrier products and lubricants are substances that act principally by physical rather than biochemical means. Barrier and lubricant substances **do not** require registration if they can be demonstrated that they:

    a. Chemically inert or act principally by physical rather than biochemical means;
    b. Applied topically to animals;
    c. Contain no antiseptic, antimicrobial, antibiotic or other active constituent; and
    d. No claim other than by their physical action.

4. Examples of physical barrier products used on animals that shall be excluded from registration include:
    a. Sunscreens, when represented only as suitable as a UV filter for topical application to normal, healthy intact skin;
    b. Hoof-care and foot-care sealants, when represented only as being suitable for topical application to hooves or pads to seal in moisture, which may help reduce or prevent drying and cracking;
    c. Polymer bandages, when represented only as being suitable for topical application to skin as a wound dressing to reduce or prevent contamination and to allow inflammatory exudates to remain in contact with a wound, which may help speed up natural healing;
    d. Honey, when represented only as being suitable for topical application to skin as a wound dressing to reduce or prevent contamination and to allow inflammatory exudates to remain in contact with a wound, which may help speed up natural healing (and not represented as having an antimicrobial effect);

e. Dental sealants, when represented only as being suitable for topical application to teeth or gums to reduce or prevent contamination, which may help reduce or prevent tartar or calculus;
f. Nasal sealants or protectants like cellulose, when represented only as being suitable for topical application to nasal passages to reduce or prevent contamination from dust or allergens;
g. Lubricants used in veterinary procedures, for example as an obstetrical lubricant (provided it doesn't contain any active constituents); and
h. Eye protectant ointments, gels or drops for use in veterinary hospitals, when represented only as being suitable for topical application to eyes to protect them during anesthesia or heavy sedation when the natural blink reflex is diminished.
i. Color intensifiers for aviary birds
j. Bitterant products (typically containing denatonium benzoate) when applied to buildings or equipment (including cages, yards, stable buildings, animal rugs and non-medicated bandages) for the sole purpose of reducing or preventing biting or chewing by non-food-producing animals.

ANNEX E

LIST OF VETERINARY MEDICAL DEVICES THAT REQUIRE REGISTRATION

Absorbable Collagen Hemostatic Felt
Absorbent Cotton (sterile)
Arterial Venous Fistula Needle Set
Bone Wax
Blood Transfusion Set
Catheters
Cervical Collar
Collagen
Dental Filling Ally
Disposable Needles
Disposable Skin Stapler and Staples
Disposable Tissue Measuring Device
Drainage Pouches
Duodenal Tube
Endotracheal Tube
Exchange Transfusion Tray
Feeding Tube
Filter Set
Fluor Alloy Amalgam
Gauze, sterile
Implantable Staple
Infusion Administration Set
Intraocular Lenses
Intrauterine Device (IUD)
I.V. Catheter Needles
Ligating Clip Device
Lubricating Jelly
Lumbar Puncture Tray
Nasal Oxygen Cannula
Orthoplast Cervical Collar
Osteotomy Set
Oxygen Catheter
Oxygen Mask
Periodontal Bone Grafting Implant
Peritoneal Dialysis Administration Set
Heart Valves
Implantable Prostheses
Rectal Catheter
Rectal Tube
Removable Skin Staple
Rotahalers
Scalp Vein Infusion Set
Scissors Skin Retractors
Skin Traction Set
Spinal Anesthesia Tray
Stomach Bag
Stomach Tube
Suction Catheter
Surgical Blades, disposable
Surgical Gloves (sterile and unsterile)
Sutures
Suturing Needles
Synthetic Cast Padding
Syringes
Thermometers
Transfusion Set
Urethral Catheter
Urinary Drainage Tube
Urine Collecting Bag
Abdominal Pads
Sterile Products
Implants
Invasive Medical Devices

* The listing maybe updated accordingly.