DERINGER

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Food and Drug Administration (FDA) Disclaim Declaration

If the determination has been made that FDA reporting is NOT REQUIRED, please complete the following declaration. Reporting and disclaim guidance follows below.

I hereby certify that the goods entered in this shipment are **exempt** from FDA reporting requirements. The goods indicated below are disclaimed because they are not regulated or are regulated, but data is not required. **Goods that are disclaimed in error may be subject to action by FDA. By signing this form, you acknowledge that you have read the entire form and understand your responsibilities as the importer of record.**

Description of Goods: _____ Intended Use: _____

These goods are: ☐ Not Regulated, Disclaimer A

HTSUS Number(s): 10 Digits Required

Shipment Entry No., Invoice or Reference No.: _____
(Single Shipment Declarations ONLY)

Annual Certificate Period, covering from _____ to _____
(Complete ONLY for Blanket Declarations, not to exceed a year minus a day)

Company Name: _____ Account Number: _____

Address: _____

City, State/Province, and Zip/Postal Code: _____

Name of Certifying Individual: _____ Title: _____

Phone No.: _____ Email: _____

Signature: _____ Date: _____

Do I need to Report or Disclaim FDA information for my product(s)?

FDA is responsible for:

- Protecting the public health by assuring that foods (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary and properly labeled; ensuring that human and animal drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from electronic product radiation
- Ensuring cosmetics and dietary supplements are safe and properly labeled
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations

FDA separates its products into the following categories. If the product falls into one of these categories, you must report required data to FDA and should not file a disclaimer. See FDA's Importing FDA Regulated Products.

Biologics - Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available. For more information visit FDA's Importing biologics and CBER Regulated Products page.

Food and Drug Administration (FDA) Disclaim Declaration (cont.)

Cosmetics - The FDA defines a cosmetic as a product (excluding pure soap) intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance**.** Cosmetics offered for import into the United States must comply with the same FDA laws and regulations as those that are produced domestically in the United States. If you are unsure if a product is a cosmetic or a drug, visit the Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?) page for more information.

Medical Devices - To assist you in determining if your product is a medical device, you may visit the "Is the Product a Medical Device?" page. FDA regulates items you might not think of as medical devices such as sunglasses and toothbrushes. The FDA defines a medical device as:

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
- ''counterfeit devices'' which means a device, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark or imprint, or any likeness thereof, or is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, processor, packer, or distributor."

Drugs - The FDA defines a drug, in part, as "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." If you are unsure if your product is a drug or a cosmetic, visit the Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?) page for more information.

Foods - The FDA defines food as "articles used for food or drink for man or other animals..." FDA must receive notification before human or animal food is offered for import into the United States. FDA's regulation of food includes dietary supplements, food and color additives, and food contact substances. For more information visit FDA's Importing Human Foods page and Importing Animal and Veterinary Products page.

Radiation Emitting Products - FDA defines a radiation-emitting electronic product as any electrically-powered product that can emit any form of radiation on the electromagnetic spectrum. These include a variety of medical and non-medical products such as mammography devices, magnetic resonance imaging (MRI) devices, laser toys, laser pointers, liquid crystal displays (LCDs), and light emitting diodes (LEDs). For more information visit FDA's Importing Radiation-Emitting Electronic Products page.

Tobacco - The term "tobacco product" means "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)". For more information visit FDA's Importing Tobacco Products page.

Veterinary Medications - The FDA defines the term drug as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and defines a new animal drug (in part) as "any drug intended for use for animals other than man, the composition of which is not generally recognized, among experts qualified by scientific training and experience, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling." For more information visit FDA's Importing Animal and Veterinary Products page.