Doing Business in Brazil: Navigating ANVISA's Regulations

Doing business in Brazil with products regulated by the National Health Surveillance Agency (ANVISA) requires strategic planning and strict regulatory compliance. Companies in the cosmetics, food, pharmaceutical, and medical device sectors must navigate a complex framework to ensure a smooth market entry. Below are some key points.

Regulatory Approval

Any product subject to ANVISA oversight must be approved before entering the Brazilian market. This includes registration, notification, authorization, or any other regulatory clearance required. If storage is outsourced, the storage provider must be properly registered, and all necessary documentation must be available during import clearance.

Importer Requirements and Responsibilities

Foreign companies cannot register products directly with ANVISA. Instead, they must appoint a local importer or a legal representative authorized by ANVISA to perform import activities, with some exceptions.

The importer or the entity responsible for the product's registration must ensure compliance with all legal and regulatory requirements throughout the importation process, from overseas shipment to final clearance in Brazil. Partnering with a reliable local company is crucial to avoiding regulatory setbacks.

Documentation and Customs Compliance

Brazil's customs regulations impose strict documentation requirements. Essential documents include certifications, invoices, and labeling that meet local standards. Any errors or missing information can result in delays, fines, or even shipment rejection. A thorough pre-shipment review is crucial to avoid costly issues.

Regulated products must comply with the following: (i) identity and quality standards; (ii) valid expiration dates; and (iii) proper primary and secondary packaging, following Good Manufacturing Practices.

Each shipment's external packaging must be suitable for transport, handling, and storage, including (as applicable):

- Commercial name (for finished or bulk products);
- Active ingredient name (for pharmaceutical imports);
- Common or technical name (for raw materials used in pharmaceuticals, cosmetics, personal care, cleaning, diagnostic, or medical products);
- Food ingredient name;
- Batch or production lot number;
- Manufacturer's name, city, and country;
- Special storage conditions (temperature, humidity, light exposure etc.).

Labeling and Language Requirements

All regulated products must comply with Brazil's labeling rules when placed on the market. Labels must be in Brazilian Portuguese and meet specific formatting guidelines. For cosmetics and food products, ingredient lists, warnings, and nutritional information must follow strict national standards. Products with foreign-language labeling cannot be sold in Brazil, except in limited non-commercial cases.

The primary, secondary, or transport packaging must include essential information based on the product category. For example, cosmetics must display the: (i) commercial name used abroad; (ii) manufacturer's name and production site; and (iii) batch number and expiration date.

Declaring the Purpose of Importation

Exporters must clearly state the intended purpose of the product upon importation. Common purposes include trade fairs, clinical research, international donations, duty-free store supply, quality control, product registration approval, equipment testing, market research, and label or packaging evaluation. Providing accurate information is crucial to prevent regulatory issues.

Special Notes: Cannabis-derived Products

Exporting cannabis-derived products to Brazil falls under a specific regulatory framework and involves an additional set of rules. ANVISA's Resolution No. 327/2019 establishes rules for the authorization, manufacturing, and importation of cannabis-based products strictly for medical use. In general, these products must contain predominantly cannabidiol (CBD) and no more than 0.2% tetrahydrocannabinol (THC), though exceptions apply. Additionally, Resolution No. 660/2022 regulates the importation of cannabis products by individuals for personal use, subject to a doctor's prescription.

Penalties for Non-compliance

Failure to comply with ANVISA regulations constitutes a sanitary violation under Law No. 6,437/of August 20, 1977. Sanctions can include fines of up to BRL 1,500,000.00, calculated based on the specifics of the case, as well as product seizure, disposal, or interdiction. Any party involved in the infraction may be held liable.

Need Help Navigating Brazilian Regulations?

Our Life Sciences team is available to assist you with this matter and to provide any necessary clarifications to your company.