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Down the Rabbit Hole: Ensuring Compliance for Labeling Pharmaceuticals

The pharmaceutical industry is one of the most heavily regulated in the U.S. economy. Even the seemingly simple step of product labeling is subject to regulation by multiple federal agencies. Compounding the challenge: the disparate regulatory regimes are largely unreconciled, resulting in conflicting rules regarding pharmaceutical labeling. It is therefore necessary to address each set of regulations separately to ensure compliance.

The principal agency regulating the safety of pharmaceuticals is the Food and Drug Administration (FDA), which requires a label identifying the "name and place of business of the manufacturer, packer, or distributor." According to FDA regulations, providing the name of an entity on a label without qualification is a representation that the entity is the sole manufacturer of the drug. FDA regulations define the processing steps taken by a "manufacturer" and dictate labeling requirements when the manufacturing process involves multiple steps by different companies, such as mixing, granulating, milling, molding, lyophilizing, tableting, encapsulating, coating, sterilizing, and filling aerosol or gaseous drugs into dispensing containers. A company that manufactures a product off-site is permitted to identify its principal place of business, unless to do so would be "seriously misleading," as would be the case if the principal place of business were in the United States but the drug was wholly manufactured in India. Failure to comply with these regulations renders the

drug "misbranded", with all the attendant consequences.

In contrast to the FDA labeling rules, Customs and Border Protection (CBP) administers regulations implemented under the Tariff Act regarding "Country of Origin" (CoO) labeling for products originating outside of the United States. The CBP uses the "Substantial Transformation Test" in determining the CoO (unless the NAFTA Marking Rules apply). A drug's CoO is therefore the place its chemical composition was last *substantially transformed*. In cases where a product consists of materials and labor from more than one country, this test could result in very different labeling requirements than the FDA's. For example, if a drug's Active Pharmaceutical Ingredient (API) is made in Country No. 1, but it is finished into capsules in Country No. 2, the CBP's regulations require that the CoO indicate where the product's API was made.

The Department of Defense and the Department of Veteran's Affairs are large and ever-increasing consumers of pharmaceutical drugs, the procurement of which is governed by the Buy American Act and the Trade Agreements Act. The U.S. government will generally favor products made in the United States, according to a complex set of calculations. Contracts over a certain value threshold require a preference for products whose CoO (using the CBP's Substantial Transformation Test) is the United States or certain foreign countries. Failure to provide accurate

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representations concerning CoO can subject a manufacturer to penalties under the False Claims Act or criminal prosecution for fraud or false statements.

At a minimum, drugs require an FDA-compliant label identifying the place of manufacture. Where the place of manufacture and the CoO differ, two statements might be required to satisfy both FDA and CBP. Heightened scrutiny should apply to transactions with the U.S. government.

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