



UNITED STATES SENATE
SPECIAL COMMITTEE on AGING

CLEAR LABELS Act

Consumer Labeling for Enhanced API Reporting and Legitimate Accountability for Base Entity Listings (CLEAR LABELS) Act

Americans have no way of knowing where their prescription drugs, or the active pharmaceutical ingredients (APIs) used to make them, are manufactured.

Today, a significant share of generic drugs and APIs is produced overseas, often in countries with weaker regulatory oversight. Federal law does not require disclosure of a drug's country of origin, leaving patients, pharmacists, providers and purchasers in the dark about where medicines come from.

This bill would bring transparency to consumers, pharmacists, providers, and purchasers on the country of origin of pharmaceuticals and APIs and empower stakeholders with the knowledge of where their medications come from.

This bill amends the Federal Food, Drug, and Cosmetic Act by:

- **Establishing FDA Standards for Original Manufacturer Disclosure of Finished Drug Products and API**
 - Establishes a new misbranding standard under which finished drug products must identify, on the label or through a searchable electronic portal, the name and place of business of each API's original manufacturer, as well as the packer or distributor.
 - Allows manufacturers to meet the requirements by listing all potential API manufacturers.
 - Does not mandate a standardized, on-package country-of-origin label for prescription drugs.
 - Manufacturer, packer or distributor information must be readily available electronically or via a physical paper copy (package insert) upon request.
- **Defining "Original Manufacturer"**
 - Defines "original manufacturer" as the last establishment to conduct substantial manufacturing activities before the API enters interstate commerce.
 - Directs the Department of Health and Human Services to issue regulations, with a delayed effective date to account for the market's implementation.
- **Exempting Duplicative Federal Labeling Regimes**
 - This prevents duplicative or conflicting federal labeling requirements and ensures manufacturers face one clear, consistent standard.

To cosponsor, or for more information, contact Jared Honts ([Jared Honts@aging.senate.gov](mailto:Jared.Honts@aging.senate.gov)) in Chairman Scott's office.