S. 3788, Consumer Labeling for Enhanced API Reporting and Legitimate Accountability for Base Entity Listings (CLEAR LABELS) Act

Section 1. Short Title.
This section provides that the Act may be cited as the "Consumer Labeling for Enhanced API Reporting and Legitimate Accountability for Base Entity Listings Act" or the "CLEAR LABELS Act."

Section 2. Require Drug Labeling to Include Original Manufacturer and Supply Chain Information.
This section amends section 502(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(b)) to revise the information that must accompany certain drugs to avoid being deemed misbranded, subject to criminal prosecution by the Department of Justice. Specifically, this section:

- Requires that a finished drug product label must identify the name, place of business, and unique facility identifier of the manufacturer, packer, or distributor, or provide a link, barcode, QR code, or other means to access a searchable electronic portal containing that information.
- Requires an active pharmaceutical ingredient to be accompanied by a label and certificate of analysis identifying the name, place of business, and unique facility identifier of the original manufacturer.
- Requires the labeling of a finished drug product, or a searchable electronic portal accessible through the labeling, to identify the name, place of business, and unique facility identifier of the original manufacturer of each active pharmaceutical ingredient, the original manufacturer of the finished drug product, and the packer or distributor, if any.
- Allows a finished drug product with multiple potential active pharmaceutical ingredient manufacturers to satisfy the requirement by identifying all such manufacturers in the labeling or searchable electronic portal.
- Requires a manufacturer, packer, or distributor furnishing information under the amended provisions to also make the information available through a package insert or in paper form to any individual who requests a copy.
- Defines "original manufacturer" as the single last establishment to conduct substantial manufacturing activities before the active pharmaceutical ingredient or finished drug product is introduced into interstate commerce.
- Directs the Secretary of Health and Human Services to issue implementing regulations and authorizes reasonable variations or alternative placement of the required information, including by electronic means. The regulations may not take effect earlier than one year after publication of the final regulations and apply to drugs manufactured on or after the effective date.

Section 3. Exemption From Customs Country of Origin Marking Requirement.
This section amends section 304 of the Tariff Act of 1930 (19 U.S.C. 1304) to exempt finished drug products from country-of-origin marking requirements when the products are marked in accordance with the Federal Food, Drug, and Cosmetic Act provision specified in this bill.