Importation of Active Pharmaceutical Ingredients (APIs) Requirements
FD&C Act 502(f) & (o) [21 USC 352(f) & (o)] Misbranded drugs and devices (Tab C)

A drug or device shall be deemed to be misbranded—

(f) Directions for use and warnings on label
Unless its labeling bears

(1) adequate directions for use; and

(2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

(o) Drugs or devices from non-registered establishments
If it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 360 of this title, if it was not included in a list required by section 360 (j) of this title, if a notice or other information respecting it was not provided as required by such section or section 360 (k) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 360 (e) of this title as the Secretary by regulation requires.