U.S. Customs and Border Protection

Marking of Prescription Medication for Retail Sale

FACT SHEET

U.S. law provides that all products of foreign origin imported into the United States must be marked with their country of origin. This requirement protects consumers' interests by informing the ultimate purchaser as to the country of origin of the goods the U.S. consumer is purchasing, including prescribed medications. This fact sheet discusses the country of origin marking requirements applicable to prescription medications of foreign origin imported into the United States for retail sale.

General Requirements for Marking

All commodities imported into the United States must be marked with the country of origin. The country of origin is the country in which the commodity is manufactured, produced, or grown. The purpose of marking is to inform the "ultimate purchaser" in the United States of the country in which the imported article was made (or grown). This allows the prospective purchaser to make an informed purchasing decision. The ultimate purchaser is generally the last person in the United States who will receive the article in the form in which it was imported. It is imperative that the marking be in a conspicuous place, as legibly, indelibly, and permanently, as the nature of the article (or its container) will permit, and in such a manner as to indicate to the ultimate purchaser in the United States the English name of the country of origin of the article. (*See* 19 U.S.C. § 1304 and 19 C.F.R. Part 134.)

Reasons for Marking

- The consumer has a right to know.
- Allows the consumer to be selective about purchasing certain products made in certain countries.
- Allows U.S. Customs and Border Protection (CBP) to maintain commodity statistics of import volumes.
- Allows U.S. manufacturers to analyze competition.
- Allows U.S. manufacturers and/or distributors of licensed commodities to track counterfeit goods.

Marking is required by law (19 U.S.C. § 1304 and 19 C.F.R. § 134.11); however, there are exceptions to the rule. Certain commodities listed in 19 C.F.R. § 134.33 are excepted from individual country of origin marking. This list is known as the J-List. "Chemicals, drugs, medicinal, and similar substances, when imported in capsules, pills, tablets, lozenges, or troches," are excepted articles set forth on the J-List. Articles on the J-List are exempt from having to be individually marked; however, the outermost container that ordinarily reaches the ultimate purchaser of a J-List article must be marked with the country of origin of the article.

In situations where imported medication is repackaged in bottles by retail pharmacies and sold for individual use, the customer at the retail pharmacy is the last person to receive the medication in the form in which the medication is imported, and thus, is considered the ultimate purchaser for purposes of 19 U.S.C. § 1304. Therefore, the importers of medication who sell to retail pharmacies, which then repackage and sell the medication to the ultimate purchasers, must comply with the certification and notice requirements of 19 C.F.R. Part 134. In turn, all repackaged medications sold to the pharmacy customers must be marked with the country of origin on the packaging.

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Accordingly, if an article on the J-List is to be repacked in a new container for sale to an ultimate purchaser after its release from CBP custody, or if a CBP Center of Excellence and Expertise (Center) Director has reason to believe that such an article will be repacked after its release, the importer must certify to the Center Director that:

- if the importer does the repacking, the new container will be marked to indicate the country of origin of the article according to the marking requirement; and,
- if the article is intended to be sold or transferred to a subsequent purchaser or repacker, the importer will notify such purchaser or transferee, in writing, at the time of sale or transfer, that any repacking of the article must conform to the aforementioned requirements.

In any instance in which either of the above scenarios may occur, the importer, or its authorized agent, must sign a statement certifying that if the commodity will be repacked in a new container while in the importer's possession, the new container, unless excepted, will be marked in accordance with the requirements of 19 U.S.C. § 1304 and 19 C.F.R. Part 134. Furthermore, the importer, or its authorized agent, must certify that if the commodity is intended to be sold or transferred to a subsequent purchaser or repacker, the party will be notified in writing, at the time of sale or transfer, of the marking requirements.

The certification statement (example on right) may appear as a typed or stamped statement on an appropriate entry document or commercial invoice, or on a preprinted attachment to such entry document or invoice; or it may be submitted in blanket form to cover all importations of a particular product for a given period (e.g., calendar year). If the blanket procedure is used, a certification must be filed with CBP, either at the port of entry or electronically at the time of entry.

The notice statement (example on right) must be provided to the subsequent purchaser or repacker (e.g., the retail pharmacy) if the article is sold or transferred to a subsequent purchaser or repacker.

For guidance on the country of origin marking of repackaged prescription medication, please refer to Headquarters Ruling Letter ("HQ") H283420, dated June 14, 2024, available at https://rulings.cbp.gov/home.

CERTIFICATE OF MARKING BY IMPORTER—REPACKED ARTICLES SUBJECT TO MARKING

(Port of entry) _____

I, _____ of _____, certify that if the article(s) covered by this entry (entry no.(s) ____ dated ____), is (are) repacked in retail container(s) e.g., blister packs), while still in my possession, the new container(s) will not conceal or obscure the country of origin marking appearing on the article(s), or else the new container(s), unless excepted, shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the container(s) will permit, in such manner as to indicate the country of origin of the article(s) to the ultimate purchaser(s) in accordance with the requirements of 19 U.S.C. 1304 and 19 CFR part 134. I further certify that if the article(s) is (are) intended to be sold or transferred by me to a subsequent purchaser or repacker, I will notify such purchaser or transferee, in writing, at the time of sale or transfer, of the marking requirements.

Date _____

Importer _____

NOTICE TO SUBSEQUENT PURCHASER OR REPACKER

These articles are imported. The requirements of 19 U.S.C. 1304 and 19 CFR part 134 provide that the articles in their containers must be marked in a conspicuous place as legibly, indelibly and permanently as the nature of the article or container will permit, in such a manner as to indicate to an ultimate purchaser in the United States, the English name of the country of origin of the article.

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Advance Ruling Program

In order to help facilitate legitimate trade, to determine how CBP will treat a particular type of import transaction, CBP recommends requesting a binding advance ruling. Any person or business that plans to import a particular product into the United States may request a binding ruling from CBP. A ruling is a written decision in the form of a letter issued by Regulations and Rulings, pursuant to 19 C.F.R. Part 177, which informs the requester how CBP will treat a good or conveyance when it is imported into or arrives in the United States. In other words, the ruling letter may discuss the appropriate tariff classification, country of origin marking of the good, the country of origin for purposes of determining the duty rate of a good, etc., for a prospective shipment. The purpose of a ruling letter is to enable the trade to make business decisions that are dependent on how the goods will be treated upon importation. Once issued, a prospective ruling is a record that members of the trade can rely and depend on wherever the same goods are imported into the United States. Trade stakeholders are encouraged to submit ruling requests electronically via the Electronic Ruling (eRuling) Template, which is transmitted directly to the National Commodity Specialist Division (NCSD). Please visit https://erulings.cbp.gov/s/ to submit your request. To learn more about the requirements for filing a ruling request, please visit: https://www.cbp.gov/trade/rulings/eruling-requirements.

e-Allegations

If you suspect there are companies engaging in illicit trade activities and not abiding by the rules, then you are encouraged to visit CBP's e-Allegations portal. The portal provides a means for the public to report to CBP any suspected violations of trade laws or regulations related to the importation of goods into the United States. These types of violations include misclassification of merchandise, false country of origin markings, health and safety issues, valuation issues, and counterfeiting.

When filing an allegation, please be as specific, detailed, and concise as possible to help expedite the complaint. Please visit: https://eallegations.cbp.gov to report the allegation.

Contact Us

For any questions regarding the country of origin marking of prescription medication, feel free to contact the Pharmaceuticals, Health & Chemicals Center of Excellence and Expertise at: PHC_Marking@cbp.dhs.gov.