

§ 82.114 Compliance by manufacturers and importers with requirements for labeling of containers of controlled substances, or products containing controlled substances.

(a) *Compliance by manufacturers and importers with requirements for labeling of containers of controlled substances, or products containing controlled substances.* Each manufacturer of a product incorporating another product or container containing a controlled substance, to which § 82.102 (a)(1), or, (a)(2) or (b)(1) applies, that is purchased or obtained from another manufacturer or supplier, is required to pass through and incorporate the labeling information that accompanies such incorporated product in a warning statement accompanying the manufacturer's finished product. Each importer of a product, or container containing a controlled substance, to which § 82.102 (a)(1), (a)(2), or (b)(1) applies, including a component product or container incorporated into the product, that is purchased from a foreign manufacturer or supplier, is required to apply a label, or to ensure that a label has been properly applied, at the site of U.S. Customs clearance.

(b) *Reliance on reasonable belief.* The manufacturer or importer of a product that incorporates another product container from another manufacturer or supplier may rely on the labeling information (or lack thereof) that it receives with the product, and is not required to independently investigate whether the requirements of this subpart are applicable to such purchased product or container, as long as the manufacturer reasonably believes that the supplier or foreign manufacturer is reliably and accurately complying with the requirements of this subpart.

(c) *Contractual obligations.* A manufacturer's or importer's contractual relationship with its supplier under which the supplier is required to accurately label, consistent with the requirements of this subpart, any products containing a controlled substance or containers of a controlled substance that are supplied to the manufacturer or importer, is evidence of reasonable belief.

§ 82.116 Compliance by manufacturers or importers incorporating products manufactured with controlled substances.

(a) *Compliance by manufacturers or importers incorporating products manufactured with controlled substances, or importing products manufactured with controlled substances.* Each manufacturer or importer of a product incorporating another product to which § 82.102 (a)(3) or (b)(2) applies, that is purchased from another manufacturer or supplier, is not required to pass through and incorporate the labeling information that accompanies such incorporated product in a warning statement accompanying the manufacturer's or importer's finished product. Importers of products to which § 82.102 (a)(3) or (b)(2) applies are required to apply a label, or to ensure that a label has been properly applied at the site of U.S. Customs clearance.

(b) *Reliance on reasonable belief.* The importer of a product purchased or obtained from a foreign manufacturer or supplier, which product may have been manufactured with a controlled substance, may rely on the information that it receives with the purchased product, and is not required to independently investigate whether the requirements of this subpart are applicable to the purchased or obtained product, as long as the importer reasonably believes that there was no use of controlled substances by the final manufacturer of the product being imported.

(c) *Contractual obligations.* An importer's contractual relationship with its supplier under which the supplier is required to accurately label, consistent with the requirements of this subpart, any products manufactured with a controlled substance that are supplied to the importer, or to certify to the importer whether a product was or was not manufactured with a controlled substance is evidence of reasonable belief.

§ 82.118 Compliance by wholesalers, distributors and retailers.

(a) *Requirement of compliance by wholesalers, distributors and retailers.* All wholesalers, distributors and retailers of products or containers to which this subpart applies are required to pass through the labeling information that

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accompanies the product, except those purchasing from other manufacturers or suppliers spare parts manufactured with controlled substances and selling those parts for the demonstrable sole purpose of repair.

(b) *Reliance on reasonable belief.* The wholesaler, distributor or retailer of a product may rely on the labeling information that it receives with the product or container, and is not required to independently investigate whether the requirements of this subpart are applicable to the product or container, as long as the wholesaler, distributor or retailer reasonably believes that the supplier of the product or container is reliably and accurately complying with the requirements of this subpart.

(c) *Contractual obligations.* A wholesaler, distributor or retailer's contractual relationship with its supplier under which the supplier is required to accurately label, consistent with the requirements of this subpart, any products manufactured with a controlled substance that are supplied to the wholesaler, distributor or retailer is evidence of reasonable belief.

§ 82.120 Petitions.

(a) *Requirements for procedure and timing.* Persons seeking to apply the requirements of this regulation to a product containing a class II substance or a product manufactured with a class I or a class II substance which is not otherwise subject to the requirements, or to temporarily exempt a product manufactured with a class I substance, based on a showing of a lack of currently or potentially available alternatives, from the requirements of this regulation may submit petitions to: Labeling Program Manager, Stratospheric Protection Division, Office of Atmospheric Programs, U.S. Environmental Protection Agency, 6202-J, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Such persons must label their products while such petitions are under review by the Agency.

(b) *Requirement for adequate data.* Any petition submitted under paragraph (a) of this section shall be accompanied by adequate data, as defined in § 82.120(c). If adequate data are not included by the petitioner, the Agency may return

the petition and request specific additional information.

(c) *Adequate data.* A petition shall be considered by the Agency to be supported by adequate data if it includes all of the following:

(1) A part clearly labeled "Section I.A." which contains the petitioner's full name, company or organization name, address and telephone number, the product that is the subject of the petition, and, in the case of a petition to temporarily exempt a product manufactured with a class I substance from the labeling requirement, the manufacturer or manufacturers of that product.

(2) For petitions to temporarily exempt a product manufactured with a class I substance only, a part clearly labeled "Section I.A.T." which states the length of time for which an exemption is requested.

(3) A part clearly labeled "Section I.B." which includes the following statement, signed by the petitioner or an authorized representative:

"I certify under penalty of law that I have personally examined and am familiar with the information submitted in this petition and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information."

(4) A part clearly labeled "Section I.C." which fully explains the basis for the petitioner's request that EPA add the labeling requirements to or remove them from the product which is the subject of the petition, based specifically upon the technical facility or laboratory tests, literature, or economic analysis described in paragraphs (c) (5), (6) and (7) of this section.

(5) A part clearly labeled "Section II.A." which fully describes any technical facility or laboratory tests used to support the petitioner's claim.

(6) A part clearly labeled "Section II.B." which fully explains any values taken from literature or estimated on the basis of known information that are used to support the petitioner's claim.