spare parts from numerous bulk shipments—is exceedingly burdensome to those companies purchasing and selling the spare parts. Typically, the bulk shipment will be labeled on a shipping crate or an invoice to indicate that the parts within that shipment were manufactured with a controlled substance. The company ordering the spare parts breaks down the shipment into bins, currently necessitating a label or labeling information to be generated for each individual part contained in that shipment. In most cases, a repair person purchases hundreds of various individual spare parts at a time from the company, making the pass-through of any labeling information extremely cumbersome and time-consuming.

Many of the original manufacturers of these spare parts are foreign manufacturers, exacerbating the burden of tracking the use of controlled substances in the manufacture of each spare part in inventory. Developing and maintaining inventories of these spare parts is extremely costly, often many times more costly than the sale price of the spare parts themselves.

EPA's decision not to require manufacturers incorporating products manufactured with controlled substances to comply with the labeling pass-through requirement was based in part on the overwhelming tracking burden imposed in determining which components were actually made using a controlled substance. A similar situation exists for those purchasing spare parts for repair purposes. Many distributors stock hundreds of thousands of spare parts to be sold to repair persons. The burden of tracking each part that is to then be sold to a person using that part for repair—which is exempted from the labeling requirements—becomes overwhelming and is without environmental benefit.

Furthermore, the repair person has specific requirements for a spare part that will work with the existing product to be repaired; consumer discretion on his or her part based on the use of an ODS is unlikely. Because the repair person is not required to pass through any labeling information in the repair of the product, requiring the labeling of spare parts themselves serves no environmental benefit. Additionally, numerous companies that stock spare parts for the repair of their products have themselves totally stopped using controlled substances and are currently encouraging suppliers to use safe alternatives in manufacturing spare parts that they purchase.

In light of the information above, EPA proposed that purchasers of spare parts manufactured with a controlled

substance and purchased from a vendor for the sole purpose of repair, or distributed for purposes of repair only, not be required to pass through the labeling information.

B. Response to Comments

EPA requested comments on its proposal to exempt from the label pass-through requirement those spare parts that are to be used for repair purposes. Nine commenters agreed with the proposed spare parts exemption.

One commenter suggested EPA exempt repair parts that contain a de minimis amount of class I chemicals. The final labeling regulation states that products containing a class I substance and containers containing a class I or class II substance bear warning labels. Because spare parts containing these substances clearly fall in the category of "products containing," they are required to be labeled. However, products containing trace quantities of a class I substance as an impurity or a residue, where the controlled substance serves no useful purpose in the product, are exempted from the labeling requirements.

Two commenters stated that the labeling exemption for spare parts should apply to manufacturers as well as others involved in the distribution process because tracking and labeling requirements for these spare parts is exceedingly burdensome and time consuming. EPA disagrees with the statement that labeling of these products by the original manufacturer represents an undue burden. Tracking and labeling spare parts made with a controlled substance by the original manufacturer is comparable to that of any other manufacturer of products which require labeling. Therefore, pass-through exemptions from labeling, which does not include manufacturers, will remain as proposed.

One of these commenters added that there are instances where "currently or potentially available" alternatives have not been identified for specific applications. In this case, according to the commenter, labeling requirements for spare parts where alternatives have not been identified would penalize that industry. The original final regulations provide for exemptions from labeling requirements for products manufactured using a class I substance where there are no substitute products or processes that 1) do not rely on the use of class I substances, 2) reduce the overall risk to human health and the environment, and 3) are currently or potentially available. Manufacturers whose products meet this criteria can apply to EPA for an exemption from labeling requirements

as outlined in the original final in the section marked Petitions (§ 82.120).

Another commenter requested clarification that the exemption applies to wholly-owned subsidiaries of the manufacturers of spare parts and that individual packages that arrive under one airway bill with alternative labeling are not subject to labeling upon entry into the country. The original rule states that wholly-owned subsidiaries are part of a parent company and are subjected to the labeling regulations; therefore, the spare parts exemption also applies to these wholly-owned subsidiaries. Additionally, if a consolidated shipment is properly labeled using an alternative label, then individual packages within that shipment do not require labeling. For spare parts that fall under the exemption established in today's rulemaking, importers and distributors are only required to pass through the label when moving the labeled shipments as packaged by the manufacturer.

C. Today's Rule

In summary, EPA establishes in today's rule that purchasers of spare parts manufactured with a controlled substance and purchased from a vendor for the sole purpose of repair, or distributed for purposes of repair only, not be required to pass through the labeling information. EPA wishes to emphasize that this exemption to the pass-through requirement does not apply to products containing a controlled substance or containers of controlled substances, nor does it apply to spare parts used to manufacture products. Manufacturers of spare parts made with controlled substances are still required to apply the appropriate labels. Moreover, importers and distributors moving the labeled shipments as packaged by the manufacturer must still pass through the labeling information.

V. Clarification of the Meaning of Products "Manufactured With"

The original final rule discussed the applicability of the labeling requirements for products *manufactured with* controlled substances. Some confusion over when labeling is required for such products has emerged since the publication of that final rule. The following discussion should clarify such labeling questions.

In reviewing whether a product must be labeled, one must examine from two perspectives. Is labeling required because it is a product "containing" a controlled substance? If not, is labeling then required because it is a product