

Discussion Points –

1a. Given that ingress of volatile compounds is a problem with LDPE containers, please discuss the advantages and disadvantages of each of the approaches described below in achieving the dual aims of preserving the purity of the drug product and legibility of the label:

?? Emboss LDPE Containers

?? Unit Package Overwrap (printed foil pouch containing one embossed LDPE vial)

?? Printed and elongated bottom tabs (e.g., 3 inches long) to LDPE container that is individually overwrapped in a foil pouch

?? Paper Labels (paper glued to LDPE vial)

?? Ink without Label (ink printed directly on LDPE vial)

?? Tactile Recognition (use of textures on LDPE vial)

?? Shrink Wrap Labels (ink on plastic sheath on LDPE vial)

?? Glass ampoules (unit/single dose vial)

1b. Please identify creative solutions or alternative packaging designs that improve legibility and address the problem of ingress of chemical contaminants, and at the same time, do not create additional problems.

2. Please consider which stakeholder groups (manufacturers, practitioners, consumers, others) can best advise FDA about possible new packaging configurations that may resolve these issues.

3. Given what you have heard today, please describe an appropriate course of action to address the problem of ingress and medication errors due to legibility and similar packaging issues.

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