

10.13 - Inhaler Supplies

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

In general, only those accessories for meter dose inhalers (MDIs), Dry Powder Inhalers (DPIs), or Nasal Spray Inhalers (NS) that are included on the *New Drug Application* or *Abbreviated New Drug Application*, listed on the package insert, and specifically packaged with the drug product itself are eligible to meet the definition of a Part D drug. If the accessories (i.e., actuator, chamber) are sold separately or are not included on the drug product's NDA or ANDA, they would not meet the definition of a Part D drug.