

_____. Not corresponding to or an ISO Class II environment or better. _____

_____ Not corresponding to or better than _____ unless any 1 starts with _____.

_____ Not both are _____ hours at room temp, _____ days refrigerated, and _____ days frozen. _____ (a, b, c, d)

_____. Not corresponding to other multiple doses of sterile products contained with the administration either to multiple patients or one patient on multiple occasions. _____

_____ Not both are _____ hours at room temp, _____ days refrigerated, and _____ days frozen. _____ (a, b, c, d)

_____. Not corresponding procedures include non-sterile ingredients or devices and is expected to be quality better than ISO Class II for more than 1 hour. _____

_____ Not both are _____ hours at room temp, _____ days refrigerated, and _____ days frozen. _____ (a, b, c, d)

_____ Not the _____ for ISO product (a). _____

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U.S. Food and Drug Administration (FDA) has approved dozens of hormone therapy products for men and women including estrogen, progesterone, testosterone, and related compounds. These products have been reviewed for safety and efficacy and are indicated for treatment of symptoms resulting from hormonal changes associated with menopause or other endocrine-based disorders. In recent decades, an increasing number of health care providers and patients have turned to custom formulated or compounded drug preparations as an alternative to FDA approved drug products for hormone related health concerns. These compounded hormone preparations are often marketed as bioequivalent or natural and are commonly referred to as compounded bioequivalent hormone therapy (cBHT). In light of the fast growing popularity of cBHT preparations, the clinical utility of these compounded preparations is a substantial public health concern for various stakeholders including medical practitioners, patients, health advocacy organizations, and federal and state public health agencies. This report examines the clinical utility and uses of cBHT drug preparations and reviews the available evidence that would support marketing claims of the safety and effectiveness of cBHT preparations. It also assesses whether the available evidence suggests that these preparations have clinical utility and safety profiles warranting their clinical use and identifies patient populations that might benefit from cBHT preparations in lieu of FDA approved BHT.

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