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We are often asked, "Are pellets FDA approved? "

The pellets we use in our therapy are derived from NDC 17-beta estradiol and NDC testosterone. The NDC designation is maintained by the FDA in this list of medicines approved for human use under Section 510 of the Food, Drug and Cosmetics Act. HOWEVER - the pellets are compounded, not manufactured. The FDA delegates its authority of oversight and regulation of compounded medicines to each individual State's Board of Pharmacy, under FDA Policy as explained below:

"FDA views traditional pharmacy compounding as the combining, mixing, or altering of ingredients to create a customized medication for an individual patient in response to a licensed practitioner's prescription. In its simplest form, it may involve taking an approved drug substance and making a new formulation to meet the medical needs of a specific patient. For example, it may involve formulating the product without a dye or preservative in response to a patient allergy. Or it might involve making a suspension or suppository dosage form for a child or elderly patient who has difficulty swallowing a tablet or a capsule. These traditional forms of pharmacy compounding are an important component of our pharmaceutical armamentarium." **SOURCE: FDA.gov**

The pellets, and our therapy, are crafted and designed for the individual patient to offer bio natural hormones in a compounded form for replacement therapy where manufactured alternatives are not available. FDA has delegated enforcement and oversight of compounded medicines to the States and says, **"FDA has exercised enforcement discretion to allow these legitimate forms of pharmacy compounding, which are regulated under state laws governing the practice of pharmacy."** **SOURCE: FDA.gov**

The pellets are compounded to dosage specified for the individual patient by the State's licensed Provider, (physician, advanced nurse practitioner or physician's assistant), each licensed from their respective State.

The pharmacies we use are fully accredited by PCAB or IACP. These accreditations are not easy to come by. To learn more about PCAB Accreditation please visit www.pcab.org, for IACP please visit www.iapcrx.org. In addition, all fully meet requirements of USP/NF 797 and use ISO 5 Class 100 Clean Rooms for processing.