FDA Continues Enforcement Crackdown on Unlawful Compounding

Alan G. Minsk and William H. Kitchens

The Food and Drug (FDA) Administration continues its enforcement action against compounding operations that violate the law. In at least four Warning Letters issued in 2014, FDA reiterated its enforcement policy on compounding drugs, and noted, in all cases, the pharmacies were "not receiving valid prescriptions for individually-identified patients for a portion of the drug products you were producing." There were also quality and production deficiencies that presented patient safety risks.

In each Warning Letter FDA cited the Drug Quality and Security Act (DQSA) recently enacted by Congress, which continues to require valid prescriptions for individually-identified patients while eliminating advertising restrictions on compounding. Because the pharmacies failed to comply with DQSA, FDA alleged the drug products were unapproved new drugs and misbranded.

AGG Observations

1. FDA is not slowing down on its enforcement of traditional compounding operations, especially when compounders fail to require valid prescriptions for individually-identified patients. FDA's lack of sympathy is symbolically illustrated by the Agency's decision to go after Grandpa's Compounding Pharmacy, Inc.
2. All the Warning Letters referred to the DQSA, recognizing the Agency will use the recently-enacted regulation to expand oversight over compounding pharmacies.
3. FDA noted safety risks presented by quality-related operations, demonstrating that FDA intends to take a tougher stance against the production practices of compounding pharmacies.
4. FDA isn't going away. Look out Grandma.

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