Environmental Protection Agency

§ 439.41 Special definitions.

For the purpose of this subpart:

(a) **Mixing, compounding, and formulating operations** means processes that put pharmaceutical products in dosage forms.

(b) **Product** means any pharmaceutical product manufactured by blending, mixing, compounding, and formulating pharmaceutical ingredients. The term includes pharmaceutical preparations for both human and veterinary use such as ampules.

Subpart D—Mixing/Compounding and Formulation

§ 439.40 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by mixing, compounding and formulating operations.

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