Section 361 vs. Section 351: What's the difference?

Section 361 governs HCT/Ps that meet all four criteria listed in 21 CFR 1271.10(a). Products that fall under section 361 do not need an IND or premarket approval to be sold because if they retain their primary functions and are used in homologous fashion, they are considered a known quantity and thus would not warrant further investigation.

What are the Section 361 Criteria? - 21 CFR 1271.10(a):

1) The HCT/P is minimally manipulated;
2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and Either:
    - i: The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
    - ii: The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
        - a: Is for autologous use;
        - b: Is for allogeneic use in a first-degree or second-degree blood relative; or
        - c: Is for reproductive use.

In contrast, products regulated under Section 351 are regulated similarly to drugs or devices which must have an IND in effect or acquire pre-market approval to be commercially marketed. Section 351 of the PHS Act governs biological products that do not meet the criteria in 21 CFR 1271.10(a), to be regulated solely under Section 361 of the PHS Act.