Approval time for 505(b)(2) drugs is nearly five months longer than for NMEs

Streamlined development process is not facilitating shorter approval cycle

- 505(b)(2) applications accounted for 63% of 451 original new drug applications approved by the Food and Drug Administration (FDA) during 2009-15.

- Mean approval time for 505(b)(2) applications was nearly five months longer than that for new molecular entities (NMEs).

- 505(b)(2) applications received substantially fewer expedited review designations than NMEs during the same period.

- The percentage of 505(b)(2) drugs approved on the first review cycle was substantially lower than for all NMEs.

- Priority review designation did not have an impact on average 505(b)(2) application approval time.

The 505(b)(2) regulatory pathway allows for a more streamlined development and approval process by enabling drug sponsors to seek approval from the FDA using data, such as FDA findings of safety and effectiveness, previously generated for a reference drug. Tufts CSDD and Sakai Regulatory Consulting sought to determine how average approval time for these applications, which are generally smaller than new drug applications (NDAs) for NMEs, compared to average approval times for NMEs.

The results summarized in this report show that from 2009 through 2015, while the 505(b)(2) regulatory pathway has been highly successful in bringing new therapies to market, drug products approved under this pathway had a longer average approval time compared to NMEs approved during the same period. This suggests that despite these applications being based on previously approved products, drug developers should not anticipate that a 505(b)(2) application will necessarily result in a shorter approval time or limited FDA requirements. As with any drug development program, it is important to engage proactively with the FDA to better understand the data needed to bridge a 505(b)(2) program with the approved reference product.