



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

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.