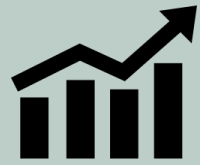


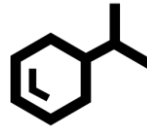
Approval in FDA 2013



FDA HAD A TOTAL OF 29 NASs APPROVED IN 2013 , WITH A MEDIAN APPROVAL TIME OF 304 DAYS



5 BIOLOGIC NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 365 DAYS



24 CHEMICAL NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 304 DAYS

6 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 270 DAYS

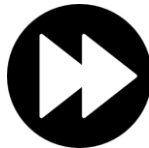


23 NASs IN OTHER THERAPY AREAS APPROVED IN 2013 WITH A MEDIAN APPROVAL TIME OF 338 DAYS



Type of Medicine

Designation and Review Type



11 EXPEDITED NASs APPROVALS IN 2013 WITH A MEDIAN APPROVAL TIME OF 239 DAYS, THIS IS A MEDIAN 125 DAYS FASTER THAN THE 18 STANDARD NAS APPROVALS IN 2013

10 ORPHAN NASs APPROVALS IN 2013 WITH A MEDIAN APPROVAL TIME OF 302 DAYS, THIS IS A MEDIAN 36 DAYS FASTER THAN THE 19 NON-ORPHAN NAS APPROVALS IN 2013



Availability in FDA



76% OF THE NASs APPROVED IN 2013 BY FDA WERE APPROVED IN FDA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT EMA, PMDA, HEALTH CANADA , SWISSMEDIC OR TGA



24% OF THE NASs APPROVED IN 2013 BY FDA WERE APPROVED AT EMA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED IN FDA

THE MEDIAN SUBMISSION GAP TO FDA FOR THESE NASs WAS 391 DAYS

