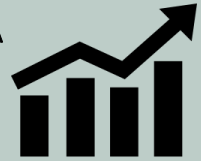


Approval at FDA 2015

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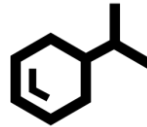
FDA (CDER AND CBER) APPROVED A TOTAL OF 51 NASs IN 2015 WITH A MEDIAN APPROVAL TIME OF 351 DAYS



FOR THE 45 NASs APPROVED BY CDER, 87% WERE 1-CYCLE REVIEWS, 9% 2-CYCLE, 4% >3-CYCLE



18 BIOLOGIC NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 356 DAYS



33 CHEMICAL NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 336 DAYS

17 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 301 DAYS



34 NASs IN OTHER THERAPY AREAS APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF 364 DAYS



Type of Medicine

Designation and Review Type



27 EXPEDITED\* NAS APPROVALS IN 2015 WITH A MEDIAN APPROVAL TIME OF 242 DAYS, THIS IS A MEDIAN 123 DAYS FASTER THAN THE 24 STANDARD NAS APPROVALS IN 2015

26 ORPHAN NAS APPROVALS IN 2015 WITH A MEDIAN APPROVAL TIME OF 333 DAYS, THIS IS A MEDIAN 32 DAYS FASTER THAN THE 25 NON-ORPHAN NAS APPROVALS IN 2015



Availability in FDA



73% OF THE NASs APPROVED IN 2015 BY FDA WERE APPROVED BY FDA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT EMA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA



27% OF THE NASs APPROVED IN 2015 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 179 DAYS



\*'Expedited review' refers to EMA 'Accelerated Assessment and FDA/PMDA/Health Canada/Swissmedic 'Priority Review'.

\*\*Date of submission at the first regulatory agency to the date of regulatory submission to the target agency.