

Approval at FDA 2016

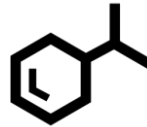
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FDA (CDER AND CBER) APPROVED A TOTAL OF 23 NASs IN 2016, WITH A MEDIAN APPROVAL TIME OF 333 DAYS



8 BIOLOGIC NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 361 DAYS



15 CHEMICAL NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 245 DAYS

5 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 179 DAYS



18 NASs IN OTHER THERAPY AREAS APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF 339 DAYS



Type of Medicine



15 EXPEDITED\* NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF 243 DAYS; THIS IS A MEDIAN 122 DAYS FASTER THAN THE 8 STANDARD NAS APPROVALS IN 2016

10 ORPHAN NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF 288 DAYS; THIS IS A MEDIAN 54 DAYS FASTER THAN THE 13 NON-ORPHAN NAS APPROVALS IN 2016



Designation and Review Type

Availability in FDA



87% OF THE NASs APPROVED IN 2016 BY FDA WERE APPROVED BY FDA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT EMA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA



13% OF THE NASs APPROVED IN 2016 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 0 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.