

2015 Submission Statistics

- Original NDA/BLAs, Amendments and Supplements: 19
- NDA/BLA Annual Reports (ARs): 68
- PSUR: 2
- ANDAs, Suitability Petitions, Amendments/Supplements: 54
- Master Files (DMFs/VMFs), Amendments and ARs: 40
- INDs and Amendments: 81
- IND ARs/DSURs: 126
- IND/NDA Safety Reports: 14
- Health Authority Meetings (regulatory strategy, requests, briefing packages, rehearsals and meeting minutes, etc.): 37
- Orphan Drug Requests, Amendments and ARs: 6
- Electronic Drug Registration and Listings (eDRLS): 62
- GDUFA Self-Identification: 13

TOTAL: 522 (258 Electronic Submissions)

In comparison to the submissions completed in 2015, **472** submissions were completed in 2014 including **188** eCTD submissions.