

## 2019 CDER Fast Track Calendar Year Approvals\*

Data as of 6/30/2019

Total of 10 Approvals

Appl Type Number	Submission Type and Number	Propriety Name	Established Name	Applicant	Approval Date	Use
BLA 761112	ORIG - 1	CABLIBI	CAPLACIZUMAB	ABLYNX NV	06-Feb-2019	Treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP) in combination with plasma exchange and immunosuppressive therapy
NDA 208711	ORIG - 1	EGATEN	TRICLABENDAZOLE	NOVARTIS PHARMACEUTICALS CORP	13-Feb-2019	Treatment of fascioliasis in patients 6 years of age and older
NDA 211962	ORIG - 1	VANCOMYCIN	VANCOMYCIN INJECTION	XELLIA PHARMACEUTICALS APS	15-Feb-2019	Treatment of septicemia, infective endocarditis, skin and skin structure infections, bone infections, and lower respiratory tract infections
NDA 211243	ORIG - 1	SPRAVATO	ESKETAMINE	JANSSEN PHARMACEUTICALS INC	05-Mar-2019	Treatment of treatment-resistant major depression
NDA 210660	ORIG - 1	ELCYS	L-CYSTEINE HYDROCHLORIDE	EXELA PHARMA SCIENCES LLC	16-Apr-2019	newborn infants requiring total parenteral nutrition (TPN); and of adult and pediatric patients with severe liver disease who may have impaired enzymatic
NDA 209379	ORIG - 1	SELENIOS ACID	SELENIOS ACID	AMERICAN REGENT INC	30-Apr-2019	Treatment of adult and pediatric patients as a source of selenium for parental nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated
NDA 211996	ORIG - 1	VYNDAQUEL	TAFAMIDIS MEGLUMINE	FOLDRX PHARMACEUTICALS INC SUB PFIZER INC	03-May-2019	Treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.
NDA 209321	ORIG - 1	RUZURGI	AMIFAMPRIDINE (3,4-DIAMINOPYRIDINE)	JACOBUS PHARMACEUTICAL CO INC	06-May-2019	Treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to less than 17 years of age
NDA 206829	SUPPL - 8	ZERBAXA	CEFTOLOZANE AND TAZOBACTAM	CUBIST PHARMACEUTICALS LLC	03-Jun-2019	Treatment of Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia (HABP/VABP)
BLA 761063	SUPPL - 3	EMGALITY	GALCANEZUMAB	ELI LILLY AND COMPANY	04-Jun-2019	Treatment of episodic cluster headache in adults

\* NOTE: Approvals with Fast Track granted because the drug was qualified as a PEPFAR drug are excluded