CDER DRUG AND BIOLOGIC ANIMAL RULE APPROVALS

This report is updated with each Animal Rule approval.

PROPRIETARY NAME	ESTABLISHED NAME OR PROPER NAME WITH DOSAGE FORM	INDICATION	ORIGINAL APPLICANT	APPLICATION NUMBER	APPROVAL DATE
PYRIDOSTIGMINE BROMIDE	pyridostigmine bromide tablet (30mg)	For prophylaxis against the lethal effects of soman nerve agent poisoning	US Army	NDA 20414	2/5/2003
CYANOKIT	hydroxocobalamin injection, powder, lyophilized, for solution	For the treatment of known or suspected cyanide poisoning	EMD Pharmaceuticals, Inc.	NDA 22041	12/15/2006
LEVAQUIN	levofloxacin tablet	For treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* (*Y. pestis*) and prophylaxis for plague in adults and pediatric patients, 6 months of age and older	Janssen Pharmaceuticals, Inc.	NDA 20634/S-061	4/27/2012
	levofloxacin injection			NDA 20635/S-067	
	levofloxacin oral solution			NDA 21721/S-028	
RAXIBACUMAB	raxibacumab injection	For the treatment of adult and pediatric patients with inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs; also indicated for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate	Human Genome Sciences, Inc.	BLA 125349	12/14/2012
CIPRO	ciprofloxacin hydrochloride tablet	For treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* (*Y. pestis*) and prophylaxis for plague in adults and pediatric patients from birth to 17 years of age	Bayer Healthcare Pharmaceuticals, Inc.	NDA 19537/S-083	2/2/2015
	ciprofloxacin hydrochloride oral suspension			NDA 20780/S-041	
CIPRO IV	ciprofloxacin for intravenous infusion			NDA 19847/S-055 NDA 19857/S-063	
NEUPOGEN	filgrastim injection	To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)	Amgen Inc.	BLA 103353/S-5183	3/30/2015
AVELOX	moxifloxacin hydrochloride tablet	For adult patients for the treatment of plague, including pneumonic and septicemic plague, due to susceptible isolates of *Yersinia pestis* and prophylaxis of plague in adult patients	Bayer Healthcare Pharmaceuticals, Inc.	NDA 21085/S-060	5/8/2015
AVELOX IV	moxifloxacin injection			NDA 21277/S-056	

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NEULASTA	pegfilgrastim injection	To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome)	Amgen Inc.	BLA 125031/S-180	11/13/2015
ANTHIM	obiltoxaximab injection	Indicated in adult and pediatric patients for treatment of inhalational anthrax due to *B. anthracis* in combination with appropriate antibacterial drugs and, for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate	Elusys Therapeutics, Inc.	BLA 125509	3/18/2016
LEUKINE	sargramostim (solution) injection sargramostim (lyophilized powder) for injection	To increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])	Sanofi-Aventis	BLA 103362/S-5240	3/29/2018
TPOXX	tecovirimat capsule, for oral use	For the treatment of human smallpox disease caused by variola virus in adults and pediatric patients weighing at least 13 kg Patient population expanded to adult and pediatric patients weighing at least 3 kg	SIGA Technologies, Inc.	NDA 208627 NDA 208627/S-007	7/13/2018 5/18/2022
	tecovirimat injection, for intravenous use	For the treatment of human smallpox disease caused by variola virus in adults and pediatric patients weighing at least 3 kg		NDA 214518	5/18/2022
NPLATE	romiplostim for injection, for subcutaneous use	To increase survival in adults and pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS])	Amgen Inc.	BLA 125268/S-167	1/28/2021
TEMBEXA	brincidofovir oral suspension	For the treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates	Chimerix, Inc.	NDA 214460	6/4/2021
	brincidofovir tablets			NDA 214461	

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CBER REGULATED BIOLOGIC ANIMAL RULE APPROVALS					
CBER has approved four products under the Animal Rule (see bulleted list below). For more information on these CBER approvals, see CBER's Biologics Products & Establishments webpage, available at: https://www.fda.gov/BiologicsBloodVaccines/ucm121134.htm. • BAT [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)] sterile solution for injection for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients (Approval date: 3/22/2013) • ANTHRASIL [Anthrax Immune Globulin Intravenous (Human)] sterile solution for infusion for the treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs (Approval date: 3/24/2015) • BioThrax (Anthrax Vaccine Adsorbed) suspension for intramuscular or subcutaneous injection for post-exposure prophylaxis of disease following suspected or confirmed *Bacillus anthracis* exposure, when administered in conjunction with recommended antibacterial drugs (Approval date: 11/23/2015) • CYFENDUS (Anthrax Vaccine Adsorbed, Adjuvanted) suspension for intramuscular injection for post-exposure prophylaxis of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs (Approval date: 7/20/2023)				