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Pediatric medical countermeasures approved under Animal Rule

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The availability of medical countermeasures (MCMs) for use against chemical, biological, radiological and nuclear (CBRN) threats is essential. However, Food and Drug Administration (FDA) approvals are challenging, particularly for pediatric patients, due to the ethical limitations of exposing healthy human volunteers to CBRN substances to study the efficacy of such products.

Nevertheless, mechanisms such as the Animal Rule [21 CFR 601.90 Subpart H for biologics and 21 CFR 314.600 Subpart I for drugs] have increased availability of MCMs.

The Animal Rule allows the FDA to establish efficacy based on adequate and well-controlled studies in animals if human efficacy trials are unethical and field trials to study the product's effectiveness after an accidental or hostile exposure are not feasible.

The safety of the product also must be established through clinical trials with healthy human adults or from other existing human data.

Pediatric data for some products, such as antibiotics, that are approved for other indications may be used to support safety of the drug when used in the pediatric population for the proposed CBRN indication. Manufacturers are required to conduct field studies for use during an exposure incident.

Not all of the MCMs approved under the Animal Rule are labeled for use in pediatric patients. The table below lists those that are labeled for use in adults and children.

Product	Indication*	Pediatric labeling date
Biologic threats		
Levofloxacin (Levaquin)	Treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* and prophylaxis for plague in adults and pediatric patients 6 months of age and older.	April 2012
Raxibacumab	Treatment of adult and pediatric patients with inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate.	December 2012
Botulism antitoxin heptavalent (A, B, C, D, E, F, G) - (Equine) (BAT)	Treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F or G in adult and pediatric patients.	March 2013
Ciprofloxacin (Cipro)	Treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* and prophylaxis for plague in adults and pediatric	February 2015

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	patients from birth to 17 years of age.	
Anthrax immune globulin (Anthrasil) also known as AIGIV	Treatment of inhalational anthrax due to *Bacillus anthracis* in adult and pediatric patients in combination with appropriate antibacterial drugs.	March 2015
Obiltoxaximab (Anthim)	Treatment of inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax due to *B. anthracis* when alternative therapies are not available or not appropriate in adult and pediatric patients.	March 2016
Radiologic/nuclear threats		
Filgrastim (Neupogen)	To increase survival in patients acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome)	March 2015
Pegfilgrastim (Neulasta)	To increase survival in patients acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome)	November 2015

*Products are approved in adults and pediatric patients from birth unless otherwise specified.

Resources

- AAP policy statement "Medical Countermeasures for Children in Public Health Emergencies, Disasters, or Terrorism"
- FDA webpage Counterterrorism and Emerging Threats
- FDA webpage Pediatric Counter-Terrorism Measures