

FDA outlines plans to address antibiotic resistance

FDA releases five-year plan for supporting antimicrobial stewardship in veterinary settings

Today, FDA's Center for Veterinary Medicine (CVM) unveiled its [five-year action plan](#) (PDF, 282 KB) for supporting antimicrobial stewardship in veterinary settings.

This plan builds upon the important steps CVM has taken to eliminate production uses of medically important antimicrobials (i.e., antimicrobials important for treating human disease) and to bring all remaining therapeutic uses of these drugs under the oversight of licensed veterinarians.

It also supports the judicious use of antimicrobials in food-producing animals and is driven by the concept that medically important antimicrobial drugs should only be used in animals when necessary for the treatment, control or prevention of specific diseases.

[Read more about the CVM plan](#)

Related links:

- [Antimicrobial Resistance](#) - **New!** - web page with updates from across FDA
- [Remarks from FDA Commissioner Scott Gottlieb, M.D.](#), on agency plans to address antibiotic resistance at a September 14, 2018 [event](#) (the live webcast continues until 11:30 a.m. ET)

Monitoring and assessment of medical countermeasures as part of a public health emergency response

Effective medical countermeasures (MCMs) are critical to minimize morbidity and mortality when responding to chemical, biological, radiological, nuclear, or emerging infectious disease threats, so it is important to accurately assess their impact.

[Read more](#), in the *American Journal of Public Health*

Related links:

- [MCM monitoring and assessment](#)
- [Public Health Emergencies: Unpacking Medical Countermeasures Management for Preparedness and Response](#) - special supplement to the *American Journal of Public Health*, September 2018
- [MCM-Related Legal and Policy Presentations, Publications and Q&As](#), including monitoring and assessment presentations

Events

- **September 17, 2018:** [Science and Regulation of Live Microbiome-Based Products Used to Prevent, Treat, or Cure Diseases in Humans](#) (Rockville, MD)
- **October 3, 2018:** [Vaccines and Related Biological Products Advisory Committee \(VRBPAC\) public meeting](#) (Silver Spring, MD and [webcast](#)) - The VRBPAC will meet in an open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2019 southern hemisphere influenza season.
- **New! October 22, 2018:** [Science Board to the FDA public meeting](#) (Silver Spring, MD and [webcast](#)) - The [Science Board](#) will hear a response from the Center for Veterinary Medicine (CVM) to the recommendations made by the Science Board's 2017 review of CVM's [National Antibiotic Resistance Monitoring System](#) program. The Science Board will also discuss potential hazards and nutritional considerations in the production of food derived from animal cell culture technologies.
- **October 29-30, 2018:** Save the date for [BARDA Industry Day](#) (Washington, DC) - Engage and network with members of BARDA, ASPR and other government and industry stakeholders. **New:** [Registration](#) is now open.
- **New! November 13-15, 2018:** [Clinical Investigator Training Course](#) (Silver Spring, MD) - Experts from FDA, the University of Maryland, and the University of Pennsylvania will provide training in all aspects of clinical studies: preclinical and clinical science, statistical structure of trials, ethical requirements, and regulatory considerations. Registration closes on **November 6, 2018**, or when registration is full.
- **New! November 27, 2018:** [Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions public meeting](#) (Washington, DC and [webcast](#)) - This meeting will give stakeholders the opportunity to provide input on the underlying systemic causes of drug shortages, and make recommendations for actions to prevent or mitigate drug shortages. To attend in-person, [register](#) by **November 21, 2018**.

Information for industry

- **RFI:** [Development of New Antibacterial Drugs Active Against Multi-Drug Resistant Bacteria](#) - The FDA Center for Drug Evaluation and Research (CDER) [Office of Antimicrobial Products](#) issued a Request for Information (RFI) on September 11, 2018, to solicit informal input from the public and private sectors to obtain external input into developing an annual list of regulatory science initiatives specific for antimicrobial products. Respond by **October 31, 2018**.
- FDA published a proposed rule, [Medical Device Submissions: Amending Premarket Regulations that Require Multiple Copies and Specify Paper Copies to be Allowed in Electronic Format](#). The proposed rule requires medical device premarket submissions to be sent in electronic format, eliminating the need for multiple paper submissions. We are taking this action to improve the efficiency of FDA's premarket submission program for medical devices. Comment by **December 12, 2018**. (*September 13, 2018*)

More: [MCM-Related Guidance by Date](#)

In case you missed it

- September is [National Preparedness Month](#). While FDA and other agencies work hard every day to help prepare the nation for potential threats, everyone can be involved in disaster readiness. [Learn what you can do now](#), including precautions for storing water and ensuring the safety of food and medical supplies for your family and pets during and after hurricanes and other storms with heavy rain, possible flooding and power outages.
- Reminder: Professional and citizen scientists are invited to test their bioinformatics skills and software tools in a challenge to identify pathogens from the [FDA-ARGOS database](#) within host samples using NGS short-read data as part of the [precisionFDA CDRH Infectious Disease NGS Diagnostics Biothreat Challenge](#), open now through **October 4, 2018**.
- The [Preparedness Summit](#), which will be held March 26-29, 2019 in St. Louis, MO, is accepting [abstracts](#) until **September 28, 2018**.
- [FDA awards five grants to advance the development of pediatric medical devices](#) - FDA has awarded five grants totaling up to \$6 million per year over the next five years to [Pediatric Device Consortia](#) across the country that will provide advice and support services to innovators of children's medical devices. *(September 12, 2018)*
- Statement from FDA Commissioner Scott Gottlieb, MD, and Center for Devices and Radiological Health Director Jeff Shuren, MD, JD, on [agency efforts to work with tech industry to spur innovation in digital health](#) *(September 12, 2018)*
- From HHS - [ORISE Fellowships at BARDA](#) provide exciting opportunities to conduct research in areas related to clinical trial design, medical countermeasure development, or emergency health response. Apply by **September 24, 2018**.
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit www.fda.gov/jobs.

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