



NATIONAL ACTION
PLAN FOR COMBATING
ANTIBIOTIC-RESISTANT
BACTERIA

MARCH 2015



Sub-Objective 1.1.5: Streamline regulatory processes for updating and approving or clearing antibiotic susceptibility testing devices, as appropriate, so that clinicians receive up-to-date interpretive criteria to guide antibacterial drug selection.

Manufacturers of antibiotic susceptibility testing (AST) devices provide interpretive criteria that are used by healthcare providers to categorize a bacterial isolate as “susceptible” or “resistant” to particular antibiotics. However, when bacteria develop new means of resistance, the interpretive criteria may no longer be clinically useful. Rapid updating of interpretive criteria in AST devices—by manufacturers or by standards development organizations (SDOs)—is therefore essential to provide accurate information to guide appropriate drug treatment.

Milestones

Within one year:

- FDA will provide technical assistance, as appropriate, on legislative proposals being considered to streamline updating of interpretive criteria for AST devices.

Within five years:

- FDA will update AST interpretive criteria more efficiently and rapidly (e.g., by adopting criteria developed by SDOs rather than including interpretive guidelines on labels).

1.2 Eliminate the use of medically important antibiotics for growth promotion in food-producing animals and bring under veterinary oversight other in-feed and in-water uses of antibiotics that are medically important for treatment, control, and prevention of disease.

FDA’s strategy to ensure the judicious use of medically important antibiotics in animal agriculture is outlined in two guidance documents:

- FDA Guidance for Industry (GFI) #209—*The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*—is intended to limit medically important antimicrobial drugs to uses in animals that (1) are considered necessary for assuring animal health, and (2) include veterinary oversight or consultation.
- FDA Guidance for Industry (GFI) #213—*New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209*—calls for:
 - Voluntary revision of the FDA-approved use conditions on the labels of medically important antibiotics to remove production indications, such as increased rate of weight gain and improved feed efficiency.

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- Phasing in veterinary oversight of the remaining therapeutic uses of medically important antibiotics in feed or water by changing the current over-the-counter status of these drugs. Because antibiotics in feed or water are typically administered to herds or flocks of food-producing animals, in-feed or in-water antibiotic use leads to an increased risk of selecting for resistance.

Sub-Objective 1.2.1: Implement FDA GFI #213 to eliminate the use of medically important antibiotics for growth promotion in animals and bring other in-feed and in-water uses of medically important antibiotics under veterinary oversight. FDA should evaluate the adoption of the proposed changes under GFI #213 after the three-year implementation period and take further action as appropriate.

Milestones

Within one year:

- FDA will finalize changes to the Veterinary Feed Directive (VFD) regulation to encourage manufacturers to transition the dispensing status of in-feed antibiotics covered by GFI #213 from over-the-counter (OTC) to VFD status, which requires veterinary oversight. FDA will publish an enhanced summary report of antibiotics sold or distributed for use in food-producing animals from 2009 to 2013. This report will support the effort to monitor the antibiotic usage aspects of Guidance #213 (see also Objective 2.2.4).

Within three years:

- FDA, in partnership with animal drug sponsors, will complete all changes recommended by GFI #213 and GFI #209. Once these changes are complete, growth promotion uses of medically important antibiotics will no longer be permitted, and the use of medically important antibiotics in the feed or water of food-producing animals will require veterinary oversight.

Sub-Objective 1.2.2: Assess progress toward eliminating the use of medically important antibiotics for growth promotion in food-producing animals through enhanced data collection on antibiotic sales and use.

Milestones

Within five years:

- FDA, in partnership with USDA and the animal agricultural industry, will evaluate and report on the impact of GFI #213 by analyzing data on antibiotic use, including total sales of antibiotics in animal agriculture and types and prevalence of antibiotic-resistance among selected foodborne pathogens and commensals isolated from retail meat and farm animals.

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Milestones for enhancing collection of data to monitor the impact of GFI #213 in fostering the judicious use of antibiotics in food-producing animals are provided under Objective 2.4.

Sub-Objective 1.2.3: Develop and implement educational outreach efforts to ensure that veterinarians and animal producers receive information and training to support implementation of these changes.

Within three years:

- FDA will collaborate with veterinary organizations, animal producer organizations, the animal feed industry, and others to develop and implement educational outreach efforts to ensure that veterinarians and animal producers receive the necessary information and training to support implementation of GFI #213 (see also: Sub-Objective 1.3.1).

Sub-Objective 1.2.4: Optimize public awareness about progress toward eliminating the use of medically important antibiotics for animal-growth promotion.

Within one year:

- FDA will publish and maintain a public web listing of products affected by GFI #213.
- FDA will begin publishing periodic updates summarizing progress in adoption of the changes proposed in GFI #213.

Within three years:

- FDA will publish a final assessment of the progress of GFI #213 on eliminating the use of medically important antibiotics for animal-growth promotion.

1.3 Identify and implement measures to foster stewardship of antibiotics in animals.

Sub-Objective 1.3.1: Develop, implement, and measure the effectiveness of evidence-based educational outreach to veterinarians and animal producers to advance antibiotic stewardship and judicious use of antibiotics in agricultural settings.

Milestones

Within one year:

- FDA and USDA will consult with livestock and veterinary organizations on the development of educational outreach materials on judicious use of antibiotics and antibiotic stewardship, and

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will meet with the American Veterinary Medical Association and the American Association of Veterinary Medical Colleges to consider the incorporation of additional material on antibiotic resistance and antibiotic stewardship into the curricula of U.S. veterinary colleges.

- USDA will conduct assessments in various animal production and veterinary settings to identify priority areas in which research is needed to support the development and validation of stewardship activities to assure judicious antibiotic use.
- USDA will solicit applications to the USDA Antimicrobial Resistance Initiative Program, which aims to advance development and use of antibiotic stewardship practices that assure judicious use of antibiotics in agriculture. Applicants may propose a combination of activities, including research studies and development of educational and outreach materials. Projected outcomes of the educational and outreach activities include better preparation of the next generation of veterinarians and laboratory scientists. Projected outcomes of the research activities include development of sustainable strategies to mitigate antibiotic resistance (see Objective 4).

Within 3 years:

- USDA will support the distribution of educational and outreach materials on antibiotic stewardship and judicious use of antibiotics that target veterinarians, producers, educators, and consumers. These activities will be accomplished through the Antimicrobial Resistance Initiative awardees whose integrated projects are linked to the Cooperative Extension System for education and extension/outreach activities.

Sub-Objective 1.3.2: Foster collaborations and public-private partnerships with public health, pharmaceutical, and agricultural stakeholders to facilitate identification and implementation of interventions (e.g., good husbandry practices) to reduce the spread of antibiotic-resistance.

Milestones

Within one year:

- FDA and USDA will identify priority areas for research to develop and validate stewardship activities to reduce the spread of antibiotic-resistance.
- FDA and USDA will work with livestock and veterinary organizations to consider ways to develop, update, and incorporate assessments of antibiotic stewardship activities into quality assurance programs.

Within three years:

- FDA and USDA will support applied research in field settings to demonstrate the feasibility and effectiveness of stewardship programs and test and validate alternatives to traditional uses of antibiotics in agriculture.

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Within five years:

- FDA and USDA will identify validated interventions to reduce the spread of antibiotic resistance and work with public and private sector partners to incorporate them into veterinary practice.

Sub-Objective 1.3.3: Identify, develop, and revise key agricultural practices that allow timely and effective implementation of interventions that improve animal health and efficient production.

Milestones

Within three years:

- FDA and USDA will support drivers-of-change studies to determine which stewardship materials and educational approaches are most effective in improving antibiotic use practices.

Sub-Objective 1.3.4: Develop appropriate metrics to gauge the success of stewardship efforts and guide their continued evolution and optimization.

Milestones

Within three years:

- FDA and USDA will:
 - Collect additional data regarding antibiotic use and resistance in food-producing animals. These data will supplement existing surveillance data used to evaluate the impact of GFI #213 on use practices and resistance trends over time.
 - Measure changes in antibiotic stewardship programs and practices as part of quality assurance programs in cattle operations and swine and broiler chicken production.
 - Use baseline data from the National Animal Health Monitoring System (NAHMS), where available, to evaluate changes over a 5-year time horizon.