World Organisation for Animal Health

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WOAH Collaborative Centre Reports Activities 2025

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CENTRE INFORMATION

***Title of WOAH Collaborating Centre**	Veterinary Drug Regulatory Programmes
***Address of WOAH Collaborating Centre**	United States Food and Drug Administration, Center for Veterinary Medicine
***Tel:**	+1-301 348.1585
***E-mail address:**	Ellen.Hart@fda.gov
Website:	ttp://www.fda.gov/animal-veterinary
***Name Director of Institute (Responsible Official):**	Timothy Schell, PhD, Director, FDA Center for Veterinary Medicine
***Name (including Title and Position) of Head of the Collaborating Centre (WOAH Contact Point):**	Ellen J Hart, DVM, Director of International Programs & Outreach, FDA Center for Veterinary Medicine
***Name of the writer:**	Ellen J Hart, DVM

TOR 1 AND 2: SERVICES PROVIDED

1. Activities as a centre of research, expertise, standardisation and dissemination of techniques within the remit of the mandate given by WOAH

Category	Title of activity	Scope
Training, capacity building (true)	Participated in the 18th VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) Forum, Indianapolis, Indiana, USA, November 11-12, 2025	The 18th Session of the VICH Forum was held in-person. The U.S. Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) provided a presentation on the bioequivalence and biowaivers. FDA CVM also provided participants to help lead the Forum pre-meeting discussion on November 11, 2025.
Zoonoses (true)	Federal One Health Coordinating Unit (OHCU)	FDA CVM participated in the OHCU coordinating platform to strengthen One Health collaboration related to prevention, detection, control, and response for zoonotic diseases and related One Health work across the federal government. FDA CVM served on the Senior Executive Leadership group of the OHCU. FDA participated in the OHCU's One Health Federal Interagency Coordinating Committee (OH-FICC) interagency calls and led OH-FICC's diagnostics subgroup focused on animal diagnostics and testing to further interagency efforts to share information with external partners, standardize procedures, prioritize testing, and report animal test results.
Diagnosis, biotechnology and laboratory (true)	Interagency agreement between FDA and USDA	The purpose of this agreement between the FDA, Center for Veterinary Medicine (CVM) and USDA, Agricultural Research Services (ARS) is to evaluate the use of certain animal drugs as potential emergency tools to prevent the entry of and spread of New World Screwworm (NWS) in the US until the sterile fly production is sufficient to eradicate NWS.
Veterinary medicinal products (true)	44th International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Steering Committee, and 18th Forum, Indianapolis, Indiana, USA: November 10-13, 2025	Organization for discussion and agreement on harmonization of studies that should be conducted to demonstrate target animal safety, human food safety, effectiveness, pharmacovigilance activities, and quality of veterinary medicines. FDA CVM is a founding member of VICH, on the Steering Committee, and chaired and provided technical expertise for several VICH working groups. CVM also assisted in the preparation of and participated in the Forum meeting.

Food security (true)	FDA CVM provided the U.S. Delegate to Chair and provide technical expertise to Electronic Working Groups in the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)	The U.S. Delegate continued to lead the Joint CCRVDF/Codex Committee on Pesticide Residues Working Group. The U.S. Delegate Co-Chaired an Electronic Working Group (EWG) to develop action levels and guidelines to address residues of veterinary drugs in foods caused by carryover of veterinary drugs in animal feed. The U.S. Delegate participated in an EWG to extrapolate Codex Maximum Residue Limits (MRLs) to other species and tissues.
Feed safety (true)	Development of Pre-Market Feed Ingredient Guidance within the International Cooperation for the Convergence of Technical Requirements for the Assessment of Feed Ingredients (ICCF)	FDA CVM participants served on the Steering Committee and as members and Chairs of Expert Working Groups within the ICCF developing internationally harmonized guidance for technical requirements for animal feed ingredients.
Diagnosis, biotechnology and laboratory (true)	National Antimicrobial Resistance Monitoring System (NARMS)	FDA CVM, in collaboration with CVM's Vet-LIRN, CDC, USDA, EPA, and others, tracked resistance to antimicrobial drugs in animals, humans, and foods. Pilot studies to test rivers and streams for antimicrobial resistance genes and bacteria have completed the culture/isolation phase and are now analysing the data. Genomic analysis is also underway with plans to publish in 2026. Sequence data are being uploaded to the National Center for Biotechnology Information (NCBI).
Diagnosis, biotechnology and laboratory (true)	CVM's Veterinary Laboratory Investigation and Response Network (Vet-LIRN) HPAI ICE	FDA CVM Vet-LIRN, in collaboration with the FDA/IFSH joint Moffett Laboratory Proficiency Evaluation Team (LPET), the Integrated Consortium of Laboratory Networks (ICLN), and the National Animal Health Laboratory Network (NAHLN), conducted an interlaboratory comparison (ICE) study to comparatively evaluate the performance of PCR-based molecular H5N1 assays across multiple laboratories using blinded test samples. The specific objective of the interlaboratory comparison was to explore participants' ability to provide reproducible results identifying the presence or absence of HPAI virus in milk using various PCR-based methods. Extensive analysis was performed to compare methods, including sample processing, extraction kits, and PCR kits. This study had 42 government, academic, and commercial laboratories participate to help assess and improve their testing methods.
Veterinary medicinal products (true)	Annual Veterinary Dictionary for Drug Related Affairs (VeDDRA) meeting Amsterdam, Netherlands April 1 and 2, 2025	Hosted by the European Medicines Agency, VICH regions were invited to participate in the ongoing development of the VeDDRA vocabulary. VeDDRA is a list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products and has been adopted as a VICH standard vocabulary in VICH pharmacovigilance GL30. Two CVM subject matter experts participated in this meeting.
Veterinary medicinal products (true)	WOAH Electronic Expert Group to develop a user-friendly document on the prudent use of anthelmintic chemicals for the African Region	Worked with WOAH and other expert group members to develop a user-friendly document requested by African WOAH Members based on the publication, "Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species." https://www.woah.org/app/uploads/2021/12/oie-anthelmintics-prudent-and-responsible-use-final-v4-web-opt.pdf
Veterinary medicinal products (true)	Reviewed new animal drugs for food-producing and companion animals for possible approval	Reviewed animal drugs for safety and efficacy, including the safety of any food produced from treated animals. Recent drug approvals are listed here: https://www.fda.gov/animal-veterinary/approved-animal-drug-products-green-book/recent-animal-drug-approvals.
Veterinary medicinal products (true)	Reviewed, approved and/or authorized the use of products indicated for New World Screwworm myiasis in animals	FDA Conditionally Approves First Drug for Prevention and Treatment of New World Screwworm Infestations in Cattle: https://www.fda.gov/news-events/press-announcements/fda-conditionally-approves-first-drug-prevention-and-treatment-new-world-screwworm-infestations FDA Issues Emergency Use Authorization for Credelio CAT to Treat New World Screwworm in Cats: https://www.fda.gov/animal-veterinary/cvm-updates/fda-issues-emergency-use-authorization-credelio-cat-treat-new-world-screwworm-cats FDA Conditionally Approves Topical Drug for Cattle for New World Screwworm and Cattle Fever Tick: https://www.fda.gov/news-events/press-announcements/fda-conditionally-approves-topical-drug-cattle-new-world-screwworm-and-cattle-fever-tick

Food safety/security (true)	Interagency Residue Control Group (IRCG) monthly meetings	Interagency Residue Control Group (IRCG) monthly meetings with FDA. These interagency meetings are the means for FDA, U.S. Environmental Protection Agency (EPA), Centers for Disease Control and Prevention (CDC), and U.S. Department of Agriculture (USDA) agencies, such as the Food Safety Inspection Service (FSIS), the Agriculture Research Service (ARS), the Agricultural Marketing Service (AMS), and the Animal and Plant Health Inspection Service (APHIS), as well as other Federal partners as needed, to discuss emerging chemical residue exposure issues, and follow up on detected findings in domestic or imported meat, poultry, and egg products.
Zoonoses (true)	Multisectoral health challenges	With other US federal agencies, including other WOAH Collaborating Centers (CDC and USDA), and state partners, CVM coordinated the United States' One Health response to various multisectoral challenges. Preparation efforts for a potential New World Scewwworm incursion into the US included collaborating closely with interagency partners as well as with international partners and animal drug sponsors to help advance response efforts, and facilitating the review of animal drugs needed to treat and prevent NWS, including providing regulatory advice, guidance, and technical assistance. FDA CVM continued to investigate an outbreak of Avian Influenza A (H5N1) impacting poultry, dairy cows, and people in multiple states.
Antimicrobial use/resistance (true)	Coordinated revision of WOAH Chapter 2.1.1 on Antimicrobial Susceptibility Testing	FDA CVM collaborated with the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and the Japanese National Veterinary Assay Laboratory (NVAL) on revision of the WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals Chapter 2.1.1 on "Laboratory Methodologies for Bacterial Antimicrobial Susceptibility Testing" which were adopted at the 2025 WOAH General Session.
Antimicrobial use/resistance (true)	WOAH 10th Round of Data Collection for the Animal Antimicrobial Use (ANIMUSE) Global Database	FDA CVM collaborated with the U.S. National Focal Point (USDA) for WOAH to enter 2024 US annual antimicrobial sales and distribution data for reporting to ANIMUSE via the data collection template and online submission portal.
Antimicrobial use/resistance (true)	13th Antimicrobial Use (AMU) Technical Reference Group	FDA CVM participated in a virtual WOAH working group to provide input for design and implementation of an electronic platform for WOAH members to submit the antimicrobial consumption (sales or use) country data.
Antimicrobial use/resistance (true)	Transatlantic Task Force on AMR (TATFAR)- various dates throughout 2025	Multiple FDA CVM contributed to the work of various TATFAR activities as part of the 2021-2025 work plan.
Antimicrobial use/resistance (true)	Global Health Security Agenda (GHSA) AMR Action Package	FDA CVM participated in the GHSA AMR Action Package, which seeks to strategically tackle AMR by addressing human and animal health, food production, and environmental aspects through multisectoral engagement, collaboration, and technical assistance for national action plan (NAP) development and implementation.
Antimicrobial use/resistance (true)	Regulatory Agencies Global Network against AMR (RAGNA)	CVM experts participated in and contributed to discussions and the development of work products drafted by RAGNA. The objectives for this network are: • Strengthen the international collaboration between regulatory agencies against AMR • Identify concrete actions that regulatory agencies can contribute with against AMR • Exchange experiences and good practices between regulatory agencies, human- and veterinary medicines, against AMR.
Antimicrobial use/resistance (true)	Veterinary Investigation and Response Network (Vet-LIRN)	As a part of Vet-LIRN's stewardship grants, recipients produced: 17 short educational videos on antimicrobial stewardship topics for owners and veterinarians that were published online.

TOR 3: HARMONISATION OF STANDARDS

2. Proposal or development of any procedure that will facilitate harmonisation of international regulations applicable to the main fucus area for which you were designated

Proposal title	Scope/Content	Applicable Area
Translation of VICH Guidelines to Spanish and French	FDA CVM has completed translations of 16 VICH guidelines into Spanish and 12 VICH guidelines into French to increase implementation of the guidelines, and to collaborate with other National Regulatory Authorities (NRAs) to validate translations in these languages. Anticipate that the finished complement of VICH Guidelines in French and Spanish will be posted on the WOAH webpage that currently hosts translations.	Training and Education Veterinary Products
WOAH Electronic expert group developing user friendly document on prudent use of anthelmintic chemicals for African Region	FDA CVM worked with WOAH and other expert group members to develop a user-friendly document requested by African WOAH Members based on the publication, Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species. https://www.woah.org/app/uploads/2021/12/oie-anthelmintics-prudent-and-responsible-use-final-v4-web-opt.pdf	Training and Education Health Management Animal Production Veterinary Products
Provided leadership to and participated in the 44th VICH Steering Committee and 18th VICH Outreach Forum meeting, Indianapolis, Indiana, USA, November 2025	• Chaired the VICH Steering Committee • Led the FDA delegation to the VICH Steering Committee • Chaired the VICH Expert Working Groups on Safety, Pharmacovigilance, Bioequivalence, and Combination Products • Participated in all VICH Expert Working Groups.	Training and Education Veterinary Products
Collaborated with the Veterinary Drugs Directorate, Health Canada, to facilitate the simultaneous review of selected animal drugs	Held teleconferences and otherwise corresponded throughout the year with reviewers to coordinate the preapproval reviews and assessments of approximately 14 animal drugs (including drugs for food producing animals), resulting in further convergence of approaches to evaluating data that support the safety, efficacy, and quality of veterinary drugs.	Veterinary Products
Collaborated with the European Medicines Agency (EMA)	Held teleconferences and otherwise corresponded throughout the year on topics of mutual interest to both agencies.	Veterinary Products
Collaborated with the Canadian Food Inspection Agency	Held teleconferences and otherwise corresponded throughout the year on topics of mutual interest (e.g., animal food ingredients) to both agencies.	Health Management Animal Production Veterinary Products
Collaborated with the European Food Safety Authority	Held teleconferences and otherwise corresponded throughout the year on topics of mutual interest (e.g., animal food ingredients) to both agencies.	Health Management Animal Production Veterinary Products
Member of ICCF Steering Committee and Expert Working Groups	· Chaired Expert Working Group on Analytical Methods for Feed Ingredients · Participated in Expert Working Group on Effectiveness Assessment of Feed Ingredients – General Recommendations · Chaired Expert Working Group on Effectiveness Assessment of Feed Ingredients Technical Effects · Participated in Expert Working Group on Feed Ingredients Environmental Risk Assessment · Participated in Expert Working Group on Effectiveness Assessment of Feed Ingredients – Nutritional Effects	Training and Education Health Management Animal Production Veterinary Products
Collaborated with the United Kingdom's (U.K.) Veterinary Medicines Directorate	Held teleconferences and other correspondence throughout the year on topics of mutual interest to both agencies.	Veterinary Products
Collaborated with the Australian Pesticides and Veterinary Medicines Authority	Held teleconferences and other correspondence throughout the year on topics of mutual interest to both agencies.	Veterinary Products
Collaborated with New Zealand's Ministry for Primary Industries	Held teleconferences and other correspondence throughout the year on topics of mutual interest to both agencies.	Veterinary Products
Collaborated with FDA Vet-LIRN laboratories, U.S. and Canadian Veterinary Diagnostic Laboratories, European Fish Health Laboratories, and the U.K. Centre for Environment, Fisheries, and Aquaculture Science	The group worked with the Clinical and Laboratory Standards Institute (CLSI), Working Group on Aquatic Animals to propose criteria used to determine if three aquatic bacterial species have developed antimicrobial resistance (in addition to the 5 species done in 2024). The CLSI, Veterinary Antimicrobial Susceptibility Testing (VAST) subcommittee accepted the criteria to be added to the VET03S performance standards for antimicrobial susceptibility testing of bacteria isolated from aquatic animals.	Laboratory Expertise Training and Education Health Management Veterinary Products

3. In exercising your activities, have you identified any regulatory research needs* relevant for WOAH?

Yes

Research need 1

Please type the Research need: • Research that supports the development of interventions to prevent, control, or eliminate Highly Pathogenic Avian Influenza (HPAI) virus in animals, or interventions that reduce the circulation of the virus in the ecosystem. Work may also include other emerging zoonotic disease threats or One Health issues in future years.

Relevance for WOAH Disease Control, Capacity Building, Other, Standard Setting, Animal Welfare, Facilitation of international collaboration,

Relevance for the Code or Manual Code, Manual,

Field Epidemiology and Surveillance, Diagnostics, Vaccines, Therapeutics,

Animal Category Terrestrial, Aquatic,

Disease:

Avian influenza

Kind of disease (Zoonosis, Transboundary diseases) Zoonosis, Transboundary diseases,

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer:

Notes:

Answer: The FDA is continuing to partner with academic research institutions through a competitive cooperative agreement process for Animal and Veterinary Innovation Centers (AVICs) that addresses critical animal and human health needs in this priority area.

Research need 2

Please type the Research need: • Research that supports the development of intentional genomic alterations in animals and the advancement of regulatory science in this field, including the development of standardized methods and protocols to characterize intended and unintended alterations resulting from the use of genome editing technologies.

Relevance for WOAH Disease Control, Capacity Building, Other, Standard Setting, Animal Welfare, Facilitation of international collaboration,

Relevance for the Code or Manual Code, Manual,

Field Epidemiology and Surveillance, Diagnostics, Vaccines, Therapeutics, Biotechnology,

Animal Category Terrestrial, Aquatic,

Disease:

Kind of disease (Zoonosis, Transboundary diseases) Zoonosis, Transboundary diseases,

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer:

Notes:

Answer: The FDA is continuing to partner with academic research institutions through a competitive cooperative agreement process for Animal and Veterinary Innovation Centers (AVICs) that addresses critical animal and human health needs in this priority area.

Research need 3

Please type the Research need: • Research that supports the development of products for minor species, minor uses in major species (dogs, cats, horses, cattle, pigs, chickens, and turkeys), and unmet veterinary medical needs in major species that create a significant animal or public health burden.

Relevance for WOAH Disease Control, Capacity Building, Other, Standard Setting, Animal Welfare, Facilitation of international collaboration, Unmet therapeutic needs,

Relevance for the Code or Manual Code, Manual,

Field Epidemiology and Surveillance, Diagnostics, Vaccines, Therapeutics,

Animal Category Terrestrial, Aquatic,

Disease:

Kind of disease (Zoonosis, Transboundary diseases) Zoonosis, Transboundary diseases,

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer:

Notes:

Answer: The FDA is continuing to partner with academic research institutions through a competitive cooperative agreement process for Animal and Veterinary Innovation Centers (AVICs) that addresses critical animal and human health needs in this priority area. CVM also funds grant applications from institutions or organizations that propose to develop or support the development of designated new animal drugs intended for minor uses in major species or for use in minor species (MUMS), to assist in defraying the costs of qualified safety and effectiveness testing that could be

used to satisfy the requirements for FDA approval of MUMS-designated drugs.

Research need 4

Please type the Research need: Research into animal drugs to treat or prevent New World Screwworm (NWS) myiasis (i.e., larvae infestation)

Relevance for WOAH Disease Control, Capacity Building, Other, Standard Setting, Animal Welfare, Facilitation of international collaboration,

Relevance for the Code or Manual Code, Manual,

Field Epidemiology and Surveillance, Diagnostics, Vaccines, Therapeutics,

Animal Category Terrestrial, Aquatic,

Disease:

New world screwworm (Cochliomyia hominivorax)

Kind of disease (Zoonosis, Transboundary diseases) Zoonosis, Transboundary diseases,

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer:

Notes:

Answer: FDA is committed to facilitating development of, and enabling access to, animal drugs to treat or prevent New World screwworm (NWS) myiasis (i.e., larvae infestation). FDA has been working with domestic and international counterparts to review scientific literature that may help identify products to meet needs. Currently, data gaps in effectiveness, animal safety and human food safety exist. FDA has been working with international counterparts and animal drug sponsors and is reviewing scientific literature to help identify existing information about safety and effectiveness of various products. Data gaps in effectiveness, animal safety and human food safety currently exist. This may limit the availability of products for producers, veterinarians and owners in certain species and scenarios. While not a comprehensive list, FDA released Priority Data Gaps Regarding Animal Drugs to Treat and Prevent New World Screwworm (https://www.fda.gov/media/190686/download?attachment) in January 2026 to identify several data gaps that, from an FDA perspective, are the most pressing. Research in these areas would help FDA assess the effectiveness of various animal drugs in different species, which may support FDA regulatory decisions. Although FDA is unable to fund research projects in these areas at this time, the agency may be able to provide technical assistance on academic, federal, state, or industry partner NWS research proposals.

4. Did your Collaborating Centre maintain a network with other WOAH Collaborating Centres (CC), Reference Laboratories (RL), or organisations designated for the same specialty, to coordinate scientific and technical studies?

Yes

Name of WOAH CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
Diagnosis and Control of Animal Diseases and Related Veterinary Product Assessment in Asia, National Veterinary Assay Laboratory (NVAL), Ministry of Agriculture, Forestry and Fisheries (JMAFF)	Japan	Asia y el Pacífico Europa	Collaborated with NVAL on revising the WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals Chapter 2.1.1 on Laboratory Methodologies for Bacterial Antimicrobial Susceptibility Testing which was adopted at 2025 WOAH General Session.
Veterinary Medicinal Products, Agence Nationale du Médicament Vétérinaire (ANSES)	France	Europa	Worked with ANSES and WOAH on preparation for and facilitating of VICH Forum meeting, FDA project to translate VICH Guidelines to Spanish and French, user friendly guideline on prudent use of anthelmintic chemicals for the African region, and revising the WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals Chapter 2.1.1 on Laboratory Methodologies for Bacterial Antimicrobial Susceptibility Testing.
Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas, Center for Veterinary Biologics, Animal and Plant Health Inspection Service, U.S.	Ames, Iowa, USA	América	On-going work to develop, establish and revise VICH guidelines for the approval and monitoring of veterinary medicines and collaborating on FDA CVM project to

Department of Agriculture			translate VICH Guidelines to Spanish and French.
US National Antimicrobial Resistance Monitoring System network laboratories – 22 laboratories covering 22 states across the USA. *Iowa State University is also a WOAH Reference Laboratory.	Maryland, USA	América	The U.S. National Antimicrobial Monitoring System (NARMS) has ongoing partnerships with 9 universities, and 12 state public health and 1 state agricultural laboratories to monitor antimicrobial resistance from meats purchased at retail. The data collected assist FDA CVM with making regulatory decisions and are also used by FDA, CDC, and USDA to respond to outbreaks. Research studies are conducted by all three agencies to determine how antimicrobial resistance emerges, spreads, and persists.
Veterinary Laboratory Investigation and Response Network (Vet-LIRN) - 48 laboratories across the USA. *Iowa State University, Mississippi State University, and University of Arizona are also WOAH Reference Laboratories.	Maryland, USA	América	The Veterinary Laboratory Investigation and Response Network (Vet-LIRN) has ongoing partnerships with state department of agricultural laboratories and universities to foster early detection of potential issues with FDA CVM- regulated animal food products. Laboratory testing data can help identify foodborne issues, including those that make both animals and people sick as part of One Health efforts. Vet-LIRN also conducts antimicrobial resistance monitoring that helps identify potential animal health issues in collaboration with NARMS.

TOR 4 AND 5: NETWORKING AND COLLABORATION

5. Did your Collaborating Centre maintain a network with other WOAH Collaborating Centres, Reference laboratories, or organisations in other disciplines, to coordinate scientific and technical studies?

Yes

Name of WOAH CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas, Center for Veterinary Biologics, Animal and Plant Health Inspection Service, U.S. Department of Agriculture and National Center for Emerging and Infectious Diseases, U.S. Centers for Disease Control and Prevention, One Health Office	USA	Americas	Coordination around One Health initiatives in response to health events, including Highly Pathogenic Avian Influenza (HPAI) and other zoonotic events.
			Monitoring antimicrobial resistance as part of a One Health framework, including

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National Antimicrobial Resistance Monitoring System (NARMS); United States Department of Agriculture, Centers for Disease Control and Prevention	USA	Americas	understanding resistance in humans, animals, foods, and the environment. Involves coordinating routine monitoring, combining reporting in publicly accessible dashboards, and prioritizing AMR research across the agencies.

TOR 6: EXPERT CONSULTANTS

6. Did your Collaborating Centre place expert consultants at the disposal of WOAH?

Yes

Name of expert	Kind of consultancy	Subject
Dr. Ellen Hart	Coordinated FDA and subject matter expert participation as WOAH collaborating center	Engagement included outreach, coordinating technical SME review and participation, and helping to lead or coordinate activities with WOAH, other WOAH Collaborating Centers (CC) and other national regulatory agencies. Engagement includes VICH Forum, substandard and falsified veterinary products, antimicrobial use and resistance, antiparasitic resistance work, and alternatives to antimicrobials.
Dr. Amber McCoig	Provided expertise on FDA AMR policies to WOAH and WOAH Working Group on AMR	Coordinated review of species-specific annexes for the WOAH Working Group on AMR. Worked with WOAH to review, coordinate and provide SME input on AMR, extralabel use, growth promotion, food safety and antimicrobial policies.
Dr. Anna Obrien	Worked with WOAH and other WOAH collaborating centers and experts on various antiparasitic resistance-focused work as WOAH collaborating center SME.	Worked as WOAH collaborating center on FAO Acaracide initiative and on WOAH-established initiative on user friendly guidelines for the African Region based on 2021 WOAH publication on the Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species. https://www.woah.org/app/uploads/2021/12/oie-anthelmintics-prudent-and-responsible-use-final-v4-web-opt.pdf
Dr. Aimee Phillippi-Taylor	Worked with WOAH and other WOAH collaborating centers and experts on various antiparasitic resistance focused work as WOAH collaborating center	Worked as WOAH collaborating center on FAO Acaracide initiative and on WOAH-established initiative on user friendly guidelines for the African Region based on 2021 WOAH publication on the Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species. https://www.woah.org/app/uploads/2021/12/oie-anthelmintics-prudent-and-responsible-use-final-v4-web-opt.pdf
Dr. Kate Huebner	Provided subject matter expertise for WOAH AMU Technical Reference Group.	Provided U.S. contribution of antimicrobial sales and/or use data for preparation of WOAH annual report and provided assistance for development of WOAH electronic platform for submission of antimicrobial sales and/or use data.
Dr. Ron Miller	Led revision of WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals Chapter 2.1.1 on Laboratory Methodologies for Bacterial Antimicrobial Susceptibility Testing which was adopted at 2025 WOAH General Session.	Led revision of Chapter 2.1.1 in collaboration with others within FDA CVM Collaborating Center as well as other WOAH CCs (ANSES and NVAL).
Dr. Heather Tate	Provided expertise for WOAH WG on AMR	Participated in WG tasked with amending WOAH Chapter 6.8 (Harmonisation of national antimicrobial resistance surveillance and monitoring programmes) of the TAHC to include companion animals as well as recommendations for integrated surveillance, including terms of reference and prioritization of surveillance components. The group began meeting in September 2025 and will conclude in Spring 2026

TOR 7: SCIENTIFIC AND TECHNICAL TRAINING

7. Did your Collaborating Centre provide advice/services to requests from Members in your main focus area?

Yes

Shared FDA CVM's experiences, activities, and approach on One Health and the regulation of veterinary medicinal, including for minor uses and minor species, and animal food in the U.S. with numerous Member countries.

Provided feedback on the World Trade Organization's Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) notifications relevant to the regulation of VMPs and animal food in the U.S. to numerous Member countries via the notification response process.

Responded to questions related to the import and export of products regulated in the U.S. by FDA CVM from numerous Member countries.

Addressed pharmacovigilance questions about the systems/processes FDA CVM uses for adverse drug event reporting and analysis from numerous Member countries.

8. Did your Collaborating Centre provide scientific and technical training, within the remit of the mandate given by WOAH, to personnel from WOAH Members?

Yes

a) Technical visit : 0

b) Seminars : 3

c) Hands-on training courses: 0

d) Internships (>1 month) : 0

Type of technical training provided (a, b, c or d)	Content	Country of origin of the expert(s) provided with training	No. participants from the corresponding country
B	Chaired the VICH Steering Committee; led the FDA delegation to the VICH Steering Committee; chaired the VICH Expert Working Groups on Safety, Pharmacovigilance, Bioequivalence, and Combination Products; participated in all VICH Expert Working Groups	United States, Japan, Europe	44
B	FDA presented on bioequivalence and biowaivers at the 18th VICH Forum on November 11-12, 2025, in Indianapolis, Indiana, USA.	United States	20
B	CVM Public Meeting: Second Annual Animal Drug User Fee Educational Conference, July 2025	United States and 13 other countries	500

TOR 8: SCIENTIFIC MEETINGS

9. Did your Collaborating Centre organise or participate in the organisation of scientific meetings related to your main focus area on behalf of WOAH?

Yes

National/International	Title of event	Co-organiser	Date	Location	No. Participants
Internationally	VICH Forum	VICH	2025-11-11	Indianapolis, Indiana, USA	56

TOR 9: DATA AND INFORMATION DISSEMINATION

10. Publication and dissemination of any information within the remit of the mandate given by WOAH that may be useful to Members of WOAH

a) Articles published in peer-reviewed journals:

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Harrison, L., S. Mukherjee, C. Li, S. Young, Q. Zhang, and S. Zhao. 2025. Pangenomic Characterization of Campylobacter Plasmids for Enhanced Molecular Typing, Risk Assessment and Source Attribution. Pathogens. 2025, 14 (9), 936: https://doi.org/10.3390/pathogens14090936

Hsu, C.H., C. Li, L. Harrison, and S. Zhao. 2025. Genomic Structure of Class 1 and 2 Integrons in Non-typhoidal Salmonella isolated from Food Animals and Related Meat Products in the U.S. Journal of Antimicrobial Chemotherapy (JAC). Sept, 2025. https://doi.org/10.1093/jac/dkaf310

Singh, R., S. Mukherjee, L. B. Harrison, P. F. McDermott, B. Ge, C. Li, U. Dessai, G. Fortenberry, J. M. Gilbert, J. Whichard and S. Zhao. 2025. Cross Resistance among 14-, 15-, and 16-membered Ring Macrolides in Salmonella and Campylobacter. Journal of Antimicrobial Chemotherapy (JAC). April 2025. https://doi.org/10.1093/jac/dkaf094

Colwell RR, Jutla AS, Hasan N, Patz J, Madhavan G, Ottesen AR, Beck K, Bell J, Brumfield K, Collins C, Finster M. 2025. Water, Waterborne Pathogens and Public Health: Environmental Drivers. Report on an American Academy of Microbiology Colloquium

Andrea Ottesen, Brandon Kocurek, Mark Mammel, Sanchez St. Fleurant, Jaclyn Dietrich, Sarah Pauley, Stephen Cole, Shelley Rankin, Olgica Ceric.2025. Breaking the culture habit: metagenomic diagnosis of companion animal skin infections
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b) International conferences:

1

FAO Global Forum for Animal Feed and Feed Regulators, October 2025, provided recorded presentation titled "Programmes and policies in support of the sustainable development of feed value chains in the USA"

c) National conferences:

9

Pain in Animals Workshop, September 2025

- *Emily Smith, "Research collaborations to advance analgesic development: An FDA Center for Veterinary Medicine Perspective"*

NIST Genome Editing Consortium, June 2025

- *Alexis Norris, "FDA-CVM Regulatory Bioinformatics Analysis of Intentional Genomic Alterations (IGAs) in Animals"*

Eco-NAMs Webinar, September 2025

- *Wesley Hunter, "New Approach Methodologies in Ecotoxicity"*

American Academy of Veterinary Pharmacology and Therapeutics (AAVPT) 23rd Biennial Symposium, May 2025

- *Marilyn Martinez, "Insights gleaned from a seasoned scientist"*

US Animal Health Association/National Institutes for Animal Agriculture New World Screwworm Symposium, September 2025

- *Tristan Colonius, "New World Screwworm – Protecting Animal and Public Health"*

US Animal Health Association – Subcommittee on Pharmaceuticals, November 2025

- *Tristan Colonius, "New World Screwworm – Protecting Animal and Public Health"*

Food and Drug Law Institute Annual Conference, May 2025

- *Honorata Hansen, "FDA's Role in Pandemic Readiness and Response: Zoonotic Diseases and Medical Countermeasures (MCMs)"*

FDA and Parenteral Drug Association (PDA) Joint Regulatory Conference, September 2025

- *Cindy Burnsteel, "CVM Updates"*

CVM Public Meeting: ADUFA V Educational Conference, July 2025

d) Other (Provide website address or link to appropriate information):

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Revised or published the following 5 Guidance for Industry Documents:

- *Heritable Intentional Genomic Alterations in Animals: The Approval Process, CVM Guidance for Industry #187B*
- *Heritable Intentional Genomic Alterations in Animals of Food-Producing Species for Use as Models of Disease, CVM Guidance for Industry #251*
- *Type VII Veterinary Master File for Research and Development and Risk Reviews, CVM Guidance for Industry #260*
- *Animal Food Ingredient Consultation (AFIC), CVM Guidance for Industry #294*
- *Dual Labeling for Fully Approved and Conditionally Approved New Animal Drugs with a New World Screwworm-Related Indication, CVM Guidance for Industry #299*

Launched NEW Webpages dedicated to disseminating animal drug information related to the control of New World Screwworm

- *Animal Drugs for New World Screwworm*
- *New World Screwworm: Information for Veterinarians*
- *GFI #299 -Dual Labeling for Fully Approved and Conditionally Approved New Animal Drugs with a New World Screwworm-Related Indication*

AnimalDrugs@FDA (https://animaldrugsatfda.fda.gov/adafda/views/#/search) – updated to include new animal drug approvals and related documents

NARMS Database (https://www.fda.gov/animal-veterinary/national-antimicrobial-resistance-monitoring-system/narms-now-integrated-data)

Open FDA Animal and Veterinary Adverse Event Reports, https://open.fda.gov/apis/animalandveterinary/

11. What have you done in the past year to advance your area of focus, e.g. updated technology?

- *Grants were provided for CVM's Veterinary Laboratory Investigation and Response Network (Vet-LIRN) laboratories to support updated technologies, including improved next-generation sequencing capacity.*
- *Funded the Reagan-Udall Foundation for the FDA to lead an initiative to identify holistic approaches to address opportunities and challenges in animal health and veterinary medicine. The Foundation has convened an Expert Panel to conduct this work and published the report Transforming Animal Health in the U.S. for the 21st Century, in June 2025. This analysis helped CVM identify areas where new or adapted regulatory approaches are needed to accommodate innovative solutions.*
- *CVM led an FDA funded Reagan Udall Foundation report that identified opportunities for the agency to address challenges at the intersection of human and animal health sectors, including those in the ongoing response to the current H5N1 (Avian influenza) outbreak.*
- *Machine learning, plasmid characterization, and both quasi and culture independent metagenomic methods are under development to support AMR monitoring in water and animal and human food.*
- *The agency is introducing advanced AI tools internally to accelerate manually intensive tasks, freeing up expert staff to focus on in-depth scientific and regulatory evaluation. The FDA's framework for AI is built on the principle that AI is a tool to augment and assist human experts, not to replace them. For instance, an internal large-language tool, Elsa, and subsequent agentic AI capabilities have been deployed to support operational efficiency, information retrieval, administrative processes, and documentation management, while reiterating that regulatory decisions remain the responsibility of FDA staff. These systems operate within secure federal environments and are not used to evaluate safety, effectiveness, or make final regulatory decisions. The FDA is developing a risk-based regulatory framework that prioritizes patient safety, transparency, the mitigation of algorithmic bias, and robust real-world performance monitoring while fostering innovation.*
- *Leveraged Emergency Declaration and Emergency Use Authorization authority for the first time for animal drugs to prepare for potential New World Screwworm incursion into the United States.*

12. Additional comments regarding your report: