World Organisation for Animal Health

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WOAH Collaborative Centre Reports Activities 2024

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CENTRE INFORMATION

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***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
	Participated in the 17th VICH	The 17th Session of the VICH Forum was held in-

Training, capacity building (true)	(International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) Forum, Amsterdam, Netherlands, November 11-12, 2024	person. The U.S. Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) provided a presentation on the approach to unmet needs for veterinary medicinal products. FDA CVM also provided participants to help lead the Forum pre-meeting discussion on November 11, 2024.
Zoonoses (true)	One Health Federal Interagency Coordination Committee (OH-FICC)	With other US federal agencies, including other WOAH Collaborating Centers (CDC and USDA), CVM coordinated the United States' One Health response to various multisectoral challenges, including COVID-19, Highly Pathogenic Avian Influenza (HPAI), and M-pox. This included leading meetings 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)	CVM's Veterinary Laboratory Investigation and Response Network (Vet-LIRN) SARS-CoV-2 Response	From 2021-2024, FDA CVM's Vet-LIRN funded and coordinated 21 SARS-CoV-2 cooperative agreements. Vet-LIRN funded work focused on diagnostic method development for the detection of SARS-CoV-2 in domestic and production animal species, and procurement of equipment for increasing testing capability. Overall, the activities resulted in the optimization of novel detection methods based on Next Generation Sequencing, Multiplex q-RT-PCR, ELISA, and LAMP, which were used to screen over 7,000 samples from 50 animal species. This included identifying new susceptible species, such as bison. Additionally, Vet-LIRN offered four proficiency exercises to evaluate SARS-CoV-2 detection assays at veterinary diagnostic laboratories. These exercises were performed in collaboration with academia, private industry, and government partner laboratories.
Veterinary medicinal products (true)	43rd International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Steering Committee, 7th Public Meeting and 17th Forum, Amsterdam, Netherlands: November 10-15, 2024	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 presented at the Public meeting and working group chairpersons presented posters describing the ongoing work of their respective VICH working groups and were available to answer questions at

		the VICH Public Meeting. CVM also assisted in the preparation of and participated in the Forum meeting.
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.
Training, capacity building (true)	Participated in the 7th VICH Public Meeting, Amsterdam, Netherlands, November 13-14, 2024	FDA CVM chaired and provided technical expertise for several VICH working groups. The chairpersons presented posters describing the ongoing work of their respective VICH working groups and were available to answer questions at the VICH Public Meeting.
Training, capacity building (true)	Hosted "Paws, Claws, Hooves, Fins, and Feet—Advancements through a One Health Approach," a virtual One Health symposium, November, 19 2024	The goal of the symposium was to highlight FDA CVM's role in protecting human and animal health and to share information on the Center's One Health approach to: animal drug safety surveillance; animal drug development for minor species, such as honeybees, and minor uses in major species like cattle, dogs, and horses; animal cells, tissues, and cell- and tissue-based products, such as blood or platelet-rich plasma; and novel food ingredients that function in the gut of an animal to affect qualities like feed efficiency, waste output, and the reduction of pathogens in food products made from the animal. The symposium had over 700 attendees, from more than 10 countries.
Diagnosis, biotechnology, and laboratory (true)	FDA Animal Biotechnology Webinar: Bioinformatics Review of Next Generation of Sequencing Data	The webinar provided an overview of FDA CVM's bioinformatics review of next generation sequencing (NGS) data in support of the molecular characterization of intentional genomic alterations (IGAs) in animals and the process for electronically submitting NGS data using precisionFDA. https://www.fda.gov/animal-veterinary/center-veterinary-medicine-cvm-animal-biotechnology-products-resource-center/fda-announces-webinar-bioinformatics-review-next-generation-sequencing-data-animal-biotechnology
		In this two-part webinar, FDA CVM provided an overview of two guidance documents, "Guidance for Industry #187A: Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach" and

Diagnosis, biotechnology, and laboratory (true)	FDA Animal Biotechnology Webinars on GFI #187A and #187B: Heritable Intentional Genomic Alterations in Animals	"Guidance for Industry #187B: Heritable Intentional Genomic Alterations in Animals: The Approval Process." https://www.fda.gov/animal-veterinary/center-veterinary-medicine-cvm-animal-biotechnology-products-resource-center/fda-animal-biotechnology-webinars-gfi-187a-and-187b-heritable-intentional-genomic-alterations
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. Ongoing pilot studies to test rivers and streams for antimicrobial resistance genes and bacteria have completed the laboratory phase and are now analyzing the data with plans to publish in 2025. Sequence data will soon be uploaded to the National Center for Biotechnology Information.
Veterinary Medicinal Products (true)	Annual Veterinary Dictionary for Drug Related Affairs (VeDDRA) meeting Amsterdam, Netherlands April 24, 2024, with follow up sessions held June 10, 2024 and November 15, 2024	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.
		The United States (U.S.) provided the Chairperson for CCRVDF. The U.S. delegation chaired a joint electronic working group (EWG) between the CCRVDF and the Codex Committee on Pesticide

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Veterinary Medicinal Products (true)	Chaired and provided technical expertise to the 27th Meeting of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF27), Omaha, Nebraska, USA, October 2024	Residues (CCPR) to propose mechanisms and topics for the Committees to work on together. The Chairperson led CCRVDF27 in October 2024. The U.S. delegation actively participated in CCRVDF27 and continued to lead the Joint EWG. The U.S. was appointed as co-Chair of an EWG tasked with developing action levels and guidelines to address residues of veterinary drugs in foods caused by carryover of veterinary drugs in animal feed. The U.S. delegation participated in an expert panel workshop on the risk assessment and data requirements for environmental inhibitors.
Veterinary Medicinal Products (true)	Provided leadership and technical expertise to the Codex Alimentarius Commission meeting, Geneva, Switzerland, November 2024	CVM supported discussion on the maximum residue limits and new work proposals under consideration for approval and adoption. Provided background on issues arising from CCRVDF27.
Veterinary Medicinal Products (true)	Chaired and provided technical expertise to the Organisation for Economic Cooperation and Development (OECD) Working Party for the Safety of Novel Foods and Feeds, Paris, France, March 2024	CVM led the Working Party revision of the Recommendation of the Council Concerning Safety Considerations for the Applications of Recombinant DNA Organisms in Industry, Agriculture and the Environment; continued to produce consensus documents on the composition (including the range values of key nutrients, toxicants, and anti-nutrients) of plants used for food and feed for comparison to new biotechnology-derived varieties; and represented FDA and U.S. Government positions in discussions related to the safety and regulation of innovative foods and food ingredients.
Veterinary Medicinal Products (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.
		In coordination with other US federal agencies, including other WOAH Collaborating Centers (CDC

Zoonoses (true)	National One Health Framework to address zoonotic diseases and advance public health preparedness in the United States, and the One Health Coordinating Unit	and USDA), FDA CVM developed a draft national framework and participated in a 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 One Health Coordinating Unit.
Zoonoses (true)	Highly Pathogenic Avian Influenza H5N1 Response	In coordination with US federal agencies, including other WOAH Collaborating Centers (CDC and USDA) and state partners, FDA CVM continued to investigate an outbreak of Avian Influenza A (H5N1) impacting poultry, dairy cows, and people in multiple states.
Antimicrobial 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."
Antimicrobial Resistance (true)	Review of WOAH Antimicrobial Resistance/Antimicrobial Use (AMR/AMU) training modules	More than 10 FDA CVM experts reviewed and provided feedback on WOAH AMR/AMU training modules.
Antimicrobial Resistance (true)	WOAH Working Group on Antimicrobial Resistance (AMR)	FDA CVM provided species-specific lists of approved antimicrobials to support annexes of the List of Antimicrobial Agents of Veterinary Importance and review of WOAH Global Database on Antimicrobial Use.
Antimicrobial Resistance (true)	Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB)	FDA CVM participated as a member of PACCARB providing advice, information, and recommendations to the Secretary of U.S. Health and Human Services regarding programs and policies intended to support and evaluate the implementation of the U.S. government's National Action Plan and activities related to combating antibiotic-resistant bacteria.
Antimicrobial 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 2023 US annual antimicrobial sales and distribution data for reporting to ANIMUSE via the data collection template and online submission portal.

Antimicrobial 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 Resistance (true)	Transatlantic Task Force on AMR (TATFAR)- various dates throughout 2023	Multiple FDA CVM contributed to the work of various TATFAR activities as part of the 2021-2025 work plan.
Antimicrobial Resistance (true)	European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)	FDA CVM participated in the annual ESVAC network meetings and periodic calls, with the goal of sharing information about methodologies for collecting and reporting antimicrobial sales and use in animals.
Antimicrobial Resistance (true)	Tripartite/Quadripartite AMR Initiatives	FDA CVM participants served on expert committees and provided expert comments to documents related to antimicrobial resistance in the food supply.
Antimicrobial Resistance (true)	Regulatory Agencies Global Network against AMR (RAGNA)	CVM experts participated in and contributed to the development of work products published 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 Resistance (true)	Veterinary Investigation and Response Network (Vet-LIRN)	As a part of Vet-LIRN's stewardship grants, recipients produced the following: 1) 7 educational videos on antimicrobial stewardship topics for owners and veterinarians were created and published online, and 2) a manuscript was published describing the efficacy of a learning tool on responsible antimicrobial use.
Antimicrobial Resistance (true)	8th Quadrapartite TrACSS (Tracking AMR Country Self-Assessment Survey)	Responded to animal health sector questions in the TrACSS survey. Results are available on the newly updated Global Database for TrACSS.

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 currently has a funded project in-progress to compete translation of all VICH guidelines into Spanish and 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 43rd VICH Steering Committee, 17th VICH Outreach Forum meeting, and 7th public conference, Amsterdam, Netherlands, November 2024	Led the FDA delegation to the VICH Steering Committee; chaired the VICH Expert Working Groups on Safety, Pharmacovigilance, Bioequivalence, Anthelmintics, and Combination Products; and 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 15 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 and collaborated on an FDA project to translate VICH Guidelines to Spanish and French.	Veterinary Products
Collaborated with the European Medicines	Held teleconferences and otherwise corresponded throughout the year on topics of mutual interest to	Veterinary Products

Agency (EMA)	both agencies. Announced revisions to the Parallel Scientific Advice program between FDA CVM and EMA.	
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 Adsorption, Desorption, Metabolism, and Excretion Safety Assessments · Chaired Expert Working Group on Analytical Methods for Feed Ingredients · Participated in Expert Working Group on Effectiveness Assessment of Feed Ingredients · Participated in Expert Working Group on Technical Effects of Animal Feed Ingredients · Participated in Expert Working Group on Feed Ingredients Environmental Risk Assessment	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	The group worked with the Clinical and Laboratory Standards Institute (CLSI), Working Group on Aquatic Animals to propose criteria used to determine if five aquatic bacterial species have developed antimicrobial resistance. The group also proposed setting criteria for three of these five species as a group rather than individually since they are part of a genus that is hard to reliably identify to the species level. The CLSI, Veterinary Antimicrobial Susceptibility Testing (VAST) subcommittee accepted the criteria for the group as well as the other two bacterial species to be added to	Laboratory Expertise Training and Education Health Management Veterinary Products

Environment, Fisheries, and Aquaculture Science	the VET04 guideline for standard testing of bacteria isolated from aquatic animals. Additionally, the group also shared data and/or finished testing and analyses to propose criteria for another three bacterial species in 2025.	

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

Yes

Research need 1

Please type the Research need: The FDA has partnered with academic research institutions through a competitive cooperative agreement process that establishes Animal and Veterinary Innovation Centers (AVICs) and addresses critical animal and human health needs in the following priority areas: • 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. • Research that supports the development of intentional genomic alternations in animals and the advancement of regulatory science in this field, with a focus on intentional genomic alternations that support agricultural resilience, food security, animal health, or public health. • 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, Facilitation of international collaboration,

Relevance for the Code or Manual

Field Therapeutics,

Animal Category Terrestrial, Aquatic,

Disease:

Kind of disease (Zoonosis, Transboundary diseases) Zoonosis,

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:

Research need 2

Please type the Research need: 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.

Relevance for WOAH Disease Control, Other, Animal Welfare, Unmet VMP needs,

Relevance for the Code or Manual

Field Therapeutics,

Animal Category Terrestrial, Aquatic,

Disease:

Kind of disease (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:

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	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.
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. Department of Agriculture	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 translate VICH Guidelines to Spanish and French.
US National Antimicrobial Resistance Monitoring System network laboratories – 24 laboratories covering 25 states across the USA.	USA	América	The U.S. National Antimicrobial Monitoring System (NARMS) has ongoing partnerships with 9 universities, and 13 state public health and 2 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) - 47 laboratories across the USA. *Iowa State University, Mississippi State University, and University of Arizona are also WOAH	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

Reference Laboratories.			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.
National Antimicrobial Resistance Monitoring System (NARMS); United States Department of Agriculture, Centers for Disease Control and Prevention	USA	Americas	Monitoring antimicrobial resistance as part of a One Health framework, including 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 CVM's participation as WOAH collaborating center, including providing technical expertise of CVM experts	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. Don Prater	Provided expertise to the WOAH Working Group on AMR and to WOAH Aquatic Animals Technical Reference ad hoc Groups.	Development of species-specific annexes of the List of Antimicrobial Agents of Veterinary Importance and review of WOAH Global Database on Antimicrobial Use and revision of Chapter 6.10.
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	Co-lead for work with WOAH and other WOAH collaborating centers and experts on various antiparasitic resistance-focused work as WOAH collaborating center SME. Co-led work on user-friendly guidelines for the African Region.	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
		Provided U.S. contribution of antimicrobial sales and/or use data for preparation of WOAH annual

Dr. Kate Huebner	Provided subject matter expertise for WOAH AMU Technical Reference Group.	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.	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).
Linda Kim-Jung	Co-lead for electronic expert group for substandard and falsified veterinary products	On-going work to help lead development of work products dedicated to best practices for identifying and controlling the distribution of substandard and falsified veterinary products.
10+ FDA CVM Experts	Review WOAH AMR/AMU training modules	Many FDA CVM experts reviewed and provided feedback on new WOAH AMR/AMU training modules.

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 : 2000

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	Led the FDA delegation to the VICH Steering Committee; chaired the VICH Expert Working Groups on Safety, Pharmacovigilance, Bioequivalence, Anthelmintics, and Combination Products; participated in all VICH Expert Working Groups	United States, Japan, Europe	43
B	FDA presented on regulatory approaches to addressing unmet animal product needs at the 17th VICH Forum on November 12, 2024, in Amsterdam, Netherlands.	United States, Japan, Europe, Canada, Australia	18
B	CVM Public Meeting: First Annual Animal Drug User Fee Educational Conference, July 2024	United States, more than 5 other countries	600
B	FDA Foods Program Regulatory Science Conference, September 2024	United States, other countries	1
B	FDA Omics Day, September 2024	United States, more than 5 other countries	500
B	FDA Scientific Computing and Data Transformation Symposium, November 2024	United States, other countries	1
B	FDA CVM One Health Symposium 2024	United States, more than 10 other countries	600
B	2024 VICH Public Conference	26 countries, including the United States, Japan, Europe, Canada, Australia, New Zealand, Republic of Korea, Switzerland, Saudi Arabia, and Egypt	179

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

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National/International	Title of event	Co-organiser	Date	Location	No. Participants
Internationally	VICH Forum	VICH	2024-11-11	Amsterdam, Netherlands	60
Internationally	VICH Public Conference	VICH	2024-11-13	Amsterdam, Netherlands	179

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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Huebner KL, Nevius A, Chamberlain J, Bright-Ponte SJ. Mapping the future of antimicrobial use data collection in US animal agriculture: insights from FDA-funded pilot studies.
JAVMA. 2024;262(8):1013-1020. Published on-line April 24, 2024.

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b) International conferences:
17
International Feed Regulators Meeting, January 2024

Cambridge, UK, Welcome Connecting Science Conference: Antimicrobial Resistance- Genomes, Big Data and Emerging Technologies, How FDA uses big data and emerging tech for AMR monitoring, March 2024

Geneva, Switzerland, European Symposium - International Association for Food Protection, A model of One Health AMR Monitoring: The National Antimicrobial Resistance Monitoring System, April 2024

Montreal, Canada, Environmental Dimension of Antimicrobial Resistance, May 2024, Describing Antimicrobial Resistance in Surface Water in the United States

Sydney, Australia, Catalysing Australia's Biosecurity Workshop, Animal and Veterinary Innovation Agenda, May 2024

Bangkok, Thailand, Regional benchmarking workshop on AMR surveillance in human health, animal health and environment sectors, NARMS One Health Monitoring, May 2024

Saint-Brieuc, France, International Symposium on One Health, A Model of One Health Antimicrobial Resistance Monitoring: The National Antimicrobial Resistance Monitoring System, June 2024

Athens, Greece, 12th International Conference on Antimicrobial Agents in Veterinary Medicine (AAVM), June 2024

Paris, France, 91st General Session of the World Assembly of National Delegates of the World Organization for Animal Health, June 2024

Hamburg, Germany, International Society for Stem Cell Research (ISSCR) annual meeting, Caninized mice as a pre-clinical animal model, July 2024

Montreal, Canada, The International Conference on Intelligent Systems for Molecular Biology (ISMB) 2024, Using XGBoost Machine Learning to Predict Antimicrobial Resistance from WGS in NARMS program, July 2024

Cape Town, South Africa, International Symposium on Microbial Ecology, August 2024

Cape Town, South Africa, 8th World One Health Congress, Presentation: Genomic Snapshot of Klebsiella pneumoniae Complex Isolates from Clinically Ill Animals Reveals Diverse Lineages with Limited Relatedness to Human Isolates, September 2024

Seoul, South Korea, The 4th Ministry of Food and Drug Safety Global Conference on Foodborne Antimicrobial Resistance, Use of New Technologies for AMR Surveillance and Monitoring in the U.S., September 2024

Vancouver, Canada, International Society for Companion Animal Infectious Diseases Symposium 2024, Presentation: FDA CVM Efforts to Support Antimicrobial Stewardship in Companion Animal Settings, October 2024

London, U.K., Committee on Toxicity and Food Standards, October 2024

Amsterdam, Netherlands, VICH 7 Public Conference, Presentation: Updates to the Anthelmintic Guidelines, November 2024

Geneva, Switzerland (virtual attendance) International Alliance for Biological Standardization Web meeting on Avoiding Antimicrobial Resistance: Veterinary Use of Phages for Prevention, Therapy and Control of Bacterial Infections, Presentation: Regulation of Phages Used in Veterinary Medicine in the U.S., November 2024

c) National conferences:
21
American Veterinary Medical Association (AVMA) Annual Convention

Animal Agtech Innovation Summit, March 2024

National Association of State Departments of Agriculture, September 2024

World Vaccine Congress, April 2024

American Association of Extension Veterinarians (in conjunction with USAHA), Nashville, TN, October 13, 2024, Presentation: Survey of veterinarians suggests knowledge gaps regarding animal disposal following pentobarbital euthanasia

American Association of Bovine Practitioners, Columbus, OH, September 13, 2024, Presentation: Survey of veterinarians suggests knowledge gaps regarding animal disposal following pentobarbital euthanasia of cattle and small ruminants

Annual Aquaculture Drug Approval Coordination Workshop, Bozeman, MT, July 2024

U.S. Animal Health Association and American Association of Veterinary Laboratory Diagnosticians Joint Annual Meeting, November 2024
- *Emily Cornwell, Survey of veterinarians suggests knowledge gaps regarding animal disposal following pentobarbital euthanasia of animals*
- *Laura Epstein, FDA Oversight of Intentional Genomic Alterations in Animals*
- *William Flynn, 3-NOP and FDA Updates*
- *Dorothy Bailey, Minor Use and Minor Species*
- *Gregory Tyson, Vet-LIRN Updates*

FDA and Parental Drug Association (PDA) Joint Regulatory Conference, September 2024

Food and Drug Law Institute's Annual Conference, May 2024

Reagan-Udall Foundation for the FDA Annual Public Meeting, May 2024

CVM Public Meeting: First Annual Animal Drug User Fee Educational Conference, July 2024

FDA Foods Program Regulatory Science Conference, September 2024

FDA Omics Day, September 2024

FDA Scientific Computing and Data Transformation Symposium, November 2024

PDA Southeast Spring Conference, June 2024

Genome Writers Guild Conference, July 2024

Swine in Biomedical Research Conference, June 2024

Society of Toxicology, March 2024

Aquaculture America, February 2024

d) Other (Provide website address or link to appropriate information):
33
Revised or published the following 22 Guidance for Industry Documents:
- *International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Good Manufacturing Practice for Active Pharmaceutical Ingredients Used in Veterinary Medicinal Products; Draft Guidance for Industry*
- *Manufacture of Batches in Support of Original New Animal Drug Applications, Abbreviated New Animal Drug Applications, and Conditional New Animal Drug Applications; Draft Guidance for Industry*
- *Raw Data for Safety and Effectiveness Studies; Draft Guidance for Industry*
- *Veterinary Feed Directive Regulation Questions and Answers; Small Entity Compliance Guide; Guidance for Industry (Revised)*
- *Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach; Guidance for Industry*
- *Heritable Intentional Genomic Alterations in Animals: The Approval Process; Guidance for Industry*
- *International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Pharmaceutical Development; Draft Guidance for Industry*
- *International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproduction Toxicity Testing (Revision 1); Draft Guidance for Industry*
- *Demonstrating Bioequivalence for Type A Medicated Articles Containing Active Pharmaceutical Ingredient(s) Considered To Be Poorly Soluble in Aqueous Media, That Exhibit Little to No Systemic Bioavailability, and Are Locally Acting; Guidance for Industry*
- *Human User Safety in New and Abbreviated New Animal Drug Applications; Guidance for Industry*
- *Chemistry, Manufacturing, and Controls in Support of Recombinant Protein Products for Veterinary Medicinal Use; Draft Guidance for Industry*
- *Chemistry, Manufacturing, and Controls Considerations for Type A Medicated Articles; Draft Guidance for Industry*
- *Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs; Guidance for Industry*
- *Priority Zoonotic Animal Drug Designation and Review Process; Guidance for Industry*
- *International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision 2); Guidance for Industry*
- *Animal Food Ingredient Consultation; Draft Guidance for Industry*
- *Food and Drug Administration Enforcement Policy for Association of American Feed Control Officials-Defined Animal Feed Ingredients; Guidance for Industry*
- *Chemistry, Manufacturing, and Controls Technical Section Filing Strategies; Draft Guidance for Industry*
- *International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing (Revision 2); Draft Guidance for Industry*
- *Using Relative Supersaturation To Support 'Urinary Tract Health' Claims for Adult Maintenance Cat Food; Guidance for Industry*
- *Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis; Draft Guidance for Industry*

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)
NARMS 2021 Annual Report (published August 2024) – 2021 NARMS Update: Integrated Report Summaryhttps://www.fda.gov/animal-veterinary/national-antimicrobial-resistance-monitoring-system/2021-narms-update-integrated-report-summary
FDA-TRACK: Progress on FDA's Support of Antimicrobial Stewardship in Veterinary Settings, (updated December 2024),

(https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-progress-fdas-support-antimicrobial-stewardship-veterinary-settings)
New One Health webpage to outline CVM efforts in this space: https://www.fda.gov/animal-veterinary/resources-you/cvm-puts-one-health-practice-protecting-health-people-and-animals-our-shared-environment

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 the FDA will use this analysis to help CVM identify areas where new or adapted regulatory approaches may be needed to accommodate innovative solutions. How the animal health sectors integrate with One Health will also be considered in the analysis. The panel expects to release its report in the second quarter of 2025.*
- *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.*
- *FDA CVM is in the process of modernizing our pharmacovigilance software/systems. This is expected to be completed Spring 2025.*
- *Establishment of four Animal and Veterinary Innovation Centers (AVICs), recipients of funding for work to advance regulatory science and further development of innovative products and approaches to better support animal health and veterinary interventions.*

12. Additional comments regarding your report: