WOAH Collaborative Centre Reports Activities 2023

Activities in 2023

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Centre Information

Title of WOAH Collaborating Centre	Veterinary Drug Regulatory Programmes
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Name Director of Institute (Responsible Official):	Tracey Forfa, 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 Hart

TOR1 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)	Committee for Veterinary Medicines of the Americas (CAMEVET), October 30 – November 2, 2023	The American Committee for Veterinary Medicines (CAMEVET) is a regional project which aims to facilitate the harmonization of standards, records, and control of veterinary medicines among member countries. CVM participated in discussions regarding animal drug GMP inspections and inspectional findings. https://rr-americas.woah.org/en/events/xxviii-seminar-on-harmonization-of-registration-and-control-of-veterinary-medicines/
Zoonoses (true)	One Health Federal Interagency Coordination Call (OH-FICC) group	In coordination with other US federal agencies, including other WOAH Collaborating Centers (CDC and USDA), coordinates the United States' One Health response to various multisectoral challenges, including COVID-19, Avian Influenza, and M-pox. This includes animal diagnostics and testing and furthering efforts to share information, standardize procedures, prioritize testing, and report animal test results.
		In coordination with US federal agencies, including USGS and USDA NVSL/NAHLN, Vet-LIRN completed a proficiency test (PT) exercise on SARS-CoV-2

Diagnosis, biotechnology and laboratory (true)	CVM's Veterinary Laboratory Investigation and Response Network (Vet-LIRN) SARS-CoV-2 Proficiency Test	molecular detection assays being used by veterinary diagnostics laboratories. The objectives of this PT were: (1) to evaluate the ability of participants, to detect SARS-CoV-2 Omicron variant in Molecular Transport Medium (2) to evaluate participants' methods on reporting false positives due to presence of non-SARS-CoV-2 animal coronavirus and (3) to explore the ability of participants to detect SARS-CoV-2 Omicron variant in feline fecal matrix homogenate.
Veterinary medicinal products (true)	42nd VICH Steering Committee and 16th Forum, Tokyo, Japan: November 13-16, 2023	Forum 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.
Feed safety (true)	Develop Pre-Market Feed Ingredient Guidance within ICCF	Serve on Steering Committee and as members and Chairs of Expert Working Groups within the International Cooperation for the Convergence of Technical Requirement for the Assessment of Feed Ingredients (ICCF)
Training, capacity building (true)	Participated in the 16th VICH Forum, Japan, November 15, 2023	The 16th Session of the VICH Outreach Forum was held with in person and virtual participation. CVM provided a presentation on the approach to regulating generic animal drugs. CVM also provided participants for the Outreach Forum pre-meeting discussion on November 14, 2023.
Diagnosis, biotechnology and laboratory (true)	FDA Animal Biotechnology Case Study Webinar for Investigational Food Use Authorizations of Animals with Investigational Intentional Genomic Alterations	The webinar covers what an Investigational Food Use Authorization (IFUA) is; when it is appropriate to make an IFUA request; the types of data and information the FDA reviews in support of an IFUA request; three case study examples that cover different types of scenarios where developers of IGAs in animals might request IFUAs; and administrative procedures that developers of IGAs in animals follow when submitting an IFUA request, https://www.fda.gov/animal-veterinary/center-veterinary-medicine-cvm-animal-biotechnology-products-resource-center/fda-animal-biotechnology-case-study-webinar-investigational-food-use-authorizations-animals
Diagnosis, biotechnology and laboratory (true)	National Antimicrobial Resistance Monitoring System (NARMS)	CVM, in collaboration with CVM's Veterinary Investigation and Response Network (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 AMR genes and bacteria.
Veterinary medicinal products (true)	Annual VeDDRA meeting, Amsterdam, NL, April 26, 2023	Hosted by the European Medicines Agency, VICH regions are 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. CVM contributes two subject matter experts to this activity.
Veterinary medicinal products (true)	WOAH Electronic Expert Group on User Friendly document on prudent use of anthelmintic chemicals	Work with WOAH and other expert group members develop a user-friendly document requested by African colleagues based on 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	Review of animal drugs for safety, efficacy, including the safety of any food produced from treated animals.
Food Safety (true)	Chaired and provided technical expertise to the CODEX Committee on Residues of Veterinary Drugs in Food (CCRVDF), between Committee meetings	The United States provided leadership for the CCRVDF by providing the Chairperson for the Committee. The U.S. delegation chaired a joint electronic working group (EWG) between the CCRVDF and the Codex Committee on Pesticide Residues (CCPR) to propose mechanisms and topics for the Committees to work together. The Chairperson lead CCRVDF26 in February 2023. The U.S. Delegate actively participated in CCRVDF26 and continued to lead the Joint EWG.
Food Safety (true)	Provided leadership and technical expertise to the Codex Alimentarius Commission meeting, Rome, Italy, November & December 2023	Supported discussion on the maximum residue limits under consideration for adoption. Provided background on issues arising from CCRVDF26.
Food Safety (true)	Chair OECD Working Party for the Safety of Novel Foods and Feeds	Continue to produce consensus documents on the composition (including the range value of key nutrients, toxicant and antinutrutrients) of plants used for food and feed for comparison to new biotechnology-derived varieties and represent FDA and USG positions in discussions related to the safety and regulation of innovative foods and food ingredients
Food Safety (true)	Regulatory Partnership for Shrimp Safety - Confidentiality Commitment with Ecuador	As part of FDA's development of the Regulatory Partnership for Shrimp Safety, a three-country pilot program designed to ensure the safety of shrimp imported into the United States, FDA signed a Regulatory Partnership Agreement with Ecuador's seafood regulatory authority. FDA's Center for Veterinary Medicine is involved in development of these partnerships to provide expertise on the impact of shrimp food and drugs on the safety of imported shrimp, https://www.fda.gov/food/cfsan-constituent-updates/fda-signs-partnership-ecuador-enhance-safety-shrimp-imports
Food Safety (true)	Provided expertise to the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), Washington, D.C., USA, September 19-28, 2023	CVM provided a technical expert to participate in the JMPR meeting, which was held in the U.S. The expert reviewed pesticides from the toxicological end point of concern related to the impact of residues on the human intestinal microbiome, to contribute to the risk assessments requested by the CCPR.
Food Safety (true)	Interagency Residue Control Group (IRCG) monthly meetings	Interagency Residue Control Group (IRCG) monthly meetings with FDA. These interagency meetings are the means for FSIS, FDA, EPA, CDC, other USDA agencies, such as 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)	National One Health framework to address zoonotic diseases and advance public health preparedness in the United States, and the One Health Coordinating Unit	In coordination with other US federal agencies, including other WOAH Collaborating Centers (CDC and USDA), developed a draft national framework and 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.

Antimicrobial Resistance (true)	WOAH Working Group on Antimicrobial Resistance (AMR)	Respond to annual data requests from WOAH on the amount of antimicrobials intended for use in food-producing animals sold or distributed in the US. 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)	Participate as a member of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) provides advice, information, and recommendations to the Secretary of US Health and Human Services regarding programs and policies intended to support and evaluate the implementation of U.S. government activities related to combating antibiotic-resistant bacteria.
Antimicrobial Resistance (true)	WOAH 9th Round of Data Collection for ANIMUSE Global Database and 13th AMU Technical Reference Group	Collaborated with the U.S. National Focal Point (USDA), to enter US annual antimicrobial sales and distribution data for reporting to ANIMUSE via the data collection template. Also participated in a small (virtual) working group led by WOAH, in providing 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 U.S experts 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	FDA participates 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 participants provide expert comments to documents related to antimicrobial resistance in the food supply.
Antimicrobial Resistance (true)	Food and Agriculture Organization (FAO) Regional (Asia) Guideline	Participate in drafting an official FAO Regional (Asia) Guideline on surveillance and monitoring of antimicrobial resistance in bacterial pathogens of fish. Published December 2023, Monitoring and surveillance of antimicrobial resistance in bacterial pathogens from aquaculture (fao.org)

TOR3: 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
WOAH Electronic expert group developing user friendly document on prudent use of anthelmintic chemicals for African Region	Work with WOAH and other expert group members develop a user-friendly document requested by African colleagues based on 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	Led the FDA delegation to the VICH Steering Committee; chaired the	

participated in the 42nd VICH Steering Committee and 16th VICH Outreach Forum meeting, Virtual, November 13-16, 2023	VICH Expert Working Groups on Safety, Pharmacovigilance, Bioequivalence, Anthelmintics, 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 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 drug registrations.	Veterinary products
Collaborated with the European Medicines Agency	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.	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.	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 Identification and Characterization of Feed Ingredients · Participated in Expert Working Group on Feed Ingredients Environmental Safety Assessment Approach	Laboratory expertise Training and education health management Animal production Veterinary products
Collaborated with the United Kingdom's 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, US and Canadian Veterinary Diagnostic Laboratories, European Fish Health Laboratories, and the UK Centre for Environment, Fisheries, and Aquaculture Science	Conducted susceptibility tests of >500 isolates from nine bacterial fish pathogens against nine antimicrobials used in aquaculture with the goal being to establish interpretive criteria to determine antimicrobial resistance. Shared data from species with European colleagues to support other similar projects. Conducted analyses and prepared presentations to propose the interpretive criteria to the Clinical and Laboratory Standards Institute (CLSI).	Laboratory expertise Training and education health management Veterinary products

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

No

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		Region of	

organisation(s)	Location	networking Centre	Purpose
Diagnosis and Control of Animal Diseases and Related Veterinary Product Assessment in Asia, National veterinary Assay laboratory, Ministry of Agriculture	Japan	Asia and Pasific	Worked to provide a revision map for WOAH Terrestrial Chapter: lab methods antimicrobial susceptibility.
Veterinary Medicinal Products, Agence Nationale du Médicament Vétérinaire (ANSES)	France	Europe	Worked with ANSES and WOAH on preparation for and facilitating of VICH forum meeting, work on use friendly guideline on prudent use of anthelminitic chemicals for the African region and providing revision map for WOAH Terrestrial Chapter: lab methods antimicrobial susceptibility.
Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas, Center for Veterinary Biologics, Animal and Plant Health Inspection Service, Department of Agriculture	Ames, Iowa, USA	Americas	On-going work to develop, establish and revise VICH guidelines for the approval and monitoring of veterinary medicines.
US National Antimicrobial Resistance Monitoring System network laboratories – 24 laboratories covering 25 states across the USA. *Iowa State University is also a WOAH Reference Laboratory.	Maryland, USA	Americas	The US National Antimicrobial Monitoring System (NARMS) has ongoing partnerships with 9 universities, 13 state public health and 2 state agricultural laboratories to monitor antimicrobial resistance from meats purchased at retail. The data collected assist CVM with making regulatory decisions and are also used by FDA, CDC and USDA to respond to outbreaks.
Veterinary Information and Response Network (Vet-LIRN) - 47 laboratories across the USA. *Iowa State University, Mississippi State University, and University of Arizona are also WOAH Reference Laboratories.	Maryland, USA	Americas	The Veterinary Information and Response Network (Vet-LIRN) has ongoing partnerships with 9 state department of agricultural laboratories and 33 universities to foster early detection of potential issues with 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.

TOR4 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, Department of Agriculture and National Center for Emerging and Infectious Diseases, US Centers for Disease Control and Prevention, One Health Office	USA	Americas	Coordination around One Health initiatives in support of the COVID-19 pandemic and other zoonotic events, including conducting interlaboratory comparison exercises for public and private laboratories testing animal samples for SARS-CoV-2.
National Antimicrobial Resistance Monitoring System (NARMS); United States Department of Agriculture, Centers for Disease Control and Prevention, Environmental Protection Agency	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.

TOR6: EXPERT CONSULTANTS

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

Yes

NAME OF EXPERT	KIND OF CONSULTANCY	SUBJECT
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. Ellen Hart	Coordinate participation as WOAH collaborating center, including on VICH Forum, SFVP, antimicrobial use and resistsance, and antiparasitic resistance work.	Worked with WOAH to help prepare for, facilitate, and attend the VICH Forum meeting in November 2023, provide feedback on SFVP pilot, and coordinate FDA SME input as a WOAH collaborating center.
Dr. Anna Obrien	Worked with WOAH and other WOAH collaborating centers and experts on various antiparasitic resistance focused work as WOAH collaborating center SME.	Work 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
		Work as WOAH collaborating center on FAO Acaracide initiative

Dr. Aimee Phillippi-Taylor	Worked with WOAH and other WOAH collaborating centers and experts on various antiparasitic resistance focused work as WOAH collaborating center	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.	Provide U.S. contribution of antimicrobial sales and/or use data for preparation of WOAH annual report and provide assistance for development of WOAH electronic platform for submission of antimicrobial sales and/or use data.

TOR7: 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 VMPs and animal food in the USA with numerous Member countries.

Provided feedback on WTO SPS/TBT notifications relevant to the regulation of VMPs and animal food in the USA to numerous Member countries via the notification response process.

Responded to questions related to the import and export of products regulated in the USA 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	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	36
B	Presented on GMP inspections and findings and participated in panel discussion related to regulation of animal drugs at WOAH Committee for Veterinary Medicines of the Americas (CAMEVET), Virtual November 2023	Americas	200
B	FDA presented on approval of generic animal drugs at the 15th VICH Forum on November 15, 2023, in Tokyo, Japan.	United States, Japan, Europe	32

TOR8: 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 (MM/YY)	LOCATION	NO. PARTICIPANTS

International	Help develop goal/outcomes for Focal Points Training English Speaking Africa	WOAH (Maria Szabo)	2023-09-04	Malawi	21
International	VICH Forum	VICH	2023-11-14	Tokyo, Japan	51

TOR9: 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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Schwan CL, Bastos LM, Young S, Domesle K, Ge B, Hsu CH, Li C, Strain E, Vipham J, Jones C, Amachawadi R, Nagaraja TG, Trinetta V. Genotypic and Phenotypic Characterization of Antimicrobial and Heavy Metal Tolerance in Salmonella enterica and Escherichia coli Isolates from Swine Feed Mills. Journal of Food Protection. 2023 Aug;86(8):100113. PMID: 37290750.

Harrison, L., Zhao, S., Li, C., McDermott, P.F., Tyson, G.H. and Strain, E., 2023. Lociq provides a loci-seeking approach for enhanced plasmid subtyping and structural characterization. Communications Biology, 6(1), p.595. https://www.nature.com/articles/s42003-023-04981-1

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Ibrahim A, Wang F, Gary Hollenbeck R, Martinez MN, Fahmy R, Hoag SW. Development and Validation of a Stability-indicating UPLC-DAD Method for the Simultaneous Determination of Ivermectin and Praziquantel in Pharmaceutical Tablets and Dissolution Media. AAPS PharmSciTech. 2023 Oct 11;24(7):211. doi: 10.1208/s12249-023-02656-y.

Helal NA, Martinez MN, Longstaff DG, Mohamed EM, Rahman Z, Khan MA, Nutan MTH. Development and Validation of Discriminatory In-vitro Release Method for Intramammary Drug Product. Pharm Res. 2023 Oct 3. doi: 10.1007/s11095-023-03609-7.

Martinez MN, Zhao F, Longstaff DG, Gabriel JJ, Coffey MJ. Evaluating the solubility of compounds intended for intramammary infusion based upon tests conducted across a range of milk matrices. PLoS One. 2023 Jul 21;18(7):e0288780. doi: 10.1371/journal.pone.0288780. PMID: 37478109; PMCID: PMC10361461.

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Li S, Gabriel JJ, Martinez MN, Longstaff DG, Coffey MJ, Zhao F. An exploratory study of a simplified approach to evaluate drug solubility in milk related vehicles. Pharm Technol Hosp Pharm. 8(1):20230006 (2023). https://doi.org/10.1515/pthp-2023-0006.

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Suad Algarni, Steven L. Foley, Hailin Tang, Shaohua Zhao, Dereje D. Gudeta, Bijay K. Khajanchi, Steven C. Ricke and Jing Han. Development of an Antimicrobial Resistance Plasmid Transfer Gene Database for Enteric Bacteria. Front. Bioinform. 3:1279359. https://www.frontiersin.org/articles/10.3389/fbinf.2023.1279359/full
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b) International conferences:
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Keystone Symposia – Precision Genome Engineering in Wistler, BC, Canada, March 19 – 24, 2024
- *Development and Qualification of assays for generating and detecting genome editing in animal biotechnology products*

Safety Signal Detection Workshop and VeDDRA Subgroup meeting in Amsterdam, Netherlands, April 24 – 27, 2023
- *Safety Signal Management at FDA*

International Association for Food Protection Conference in Toronto, Canada, July 15 – 19, 2023
- *Metagenomic Insights into Pet Food Microbiomes and Resistomes*

International Society for Cell and Gene Therapy in Paris, France, May 29 – June 4, 2023
- *Developing cell based treatments that are both effective and safe*

The First Global Joint Human and Veterinary Medicines Regulatory Authorities Summit in Geneva, Switzerland, May 2 – 7, 2024
- *FDA CVM AMR Policies: OTC to Rx*

Joint Workshop on EMA and FDA Collaborations in Amsterdam, Netherlands, September 10 – 17, 2023
- *CVM Initiatives and Key Priorities*

Transatlantic Taskforce on Antimicrobial Resistance Meeting in Luxembourg, November 12 – 16, 2023

XXVIII Seminar on Harmonization of Registration and Control of Veterinary Medicines Americas Committee on Veterinary Medicines (CAMEVET), in Montevideo, Uruguay, October 28 – November 3, 2024
- *Experience in inspection and certification on GMP in the FDA*

OECD meeting of the Validation Methodology Group for ecotoxicity (VMG-eco) in Paris, France, October 23-24, 2023
- *Reducing the number of controls in fish early-life stage toxicity tests when solvents are required*

Alternatives to Chronic Fish Testing Workshop in Paris, France, October 25-26, 2023
- *Generating ideas for new approach methodologies to replace the chronic fish toxicity test*

International Congress of the European Association for Veterinary Pharmacology and Toxicology, July 2023
- *Meeting the therapeutic challenges facing animal health in the 21st century: regulatory challenges.*

12th World Congress on Alternatives and Animal Use in the Life Sciences, August 2023
- *Reducing the number of controls in fish early-life stage toxicity tests when solvents are required*

c) National conferences:
9

American Veterinary Medical Association (AVMA) Annual Convention
US Animal Health Association
The Society of Environmental Toxicology and Chemistry (SETAC) North America Annual Meeting, November 2023
- *Poster on Water Quality Benchmarks for New Animal Drugs*
- *Session on Pharmaceuticals in the Environment – a One Health Perspective*
- *Session on Activities of the Federal Interagency Workgroup on Pharmaceuticals in Drinking Water*
- *Poster on Environmental Considerations for Drugs used in Aquaculture*
- *Session on Analysis of pharmaceuticals, Pesticides, and other chemicals in environmental matrices to support One Health*

Aquaculture America, February 2023
- *FDA Center for Veterinary Medicine's Aquaculture Strategic Plan and Center Updates*
- *The New Animal Drug Approval Process – Highlight on Conditional Approval and Presubmission Conferences*

Society of Quality Assurance, March 2023
- *One CVM Animal Drug Review Lifecycle and CVM's Role in the BIMO Inspection Process*
- *Highlights to the Revised Questions and Answer Document for the Data Quality Webinar held June 4th and 6th, 2013 (revised 2021)*

Society of Toxicology Meeting, March 2023
- *Poster on Parallel Evaluation of Alternative Skin Barrier Models and Excised Human Skin for Dermal Absorption Studies in vitro*

American Society of Gene and Cell Therapy, May 2023
- *CVM and CBER Commonalities and Opportunities to Collaborate in the Development of Gene Therapies for Human and Veterinary Use*

Pain in Animals Workshop, September 2023
- *Assessing pain in pigs: A collaborative effort by industry, academia, and government to advance pig welfare*
- *Statistical Considerations When Using Multiple or Composite Endpoints*
- *Adaptive and Other Innovative Pain Measurement Study Design*

American College of Veterinary Internal Medicine Annual Forum, March 2023
- *Overview of oncology drug approval process for companion animals*

d) Other (Provide website address or link to appropriate information):
12
Revised or published the following XX Guidance for Industry Documents:
CVM GFI #106 The Use of Published Literature in Support of New Animal Drug Approvals
Draft CVM GFI #273 Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-273-defining-durations-use-approved-medically-important-antimicrobial-drugs-fed-food
CVM GFI #278 Human User Safety in New and Abbreviated New Animal Drug Applications
CVM GFI #282 Informed Consent Forms for Studies that Enroll Client-Owned Companion Animals
NARMS Database, https://www.fda.gov/animal-veterinary/national-antimicrobial-resistance-monitoring-system/narms-now-integrated-data
AnimalDrugs@FDA (https://animaldrugsatfda.fda.gov/adafda/views/#/search) – updated to include new animal drug approvals and related documents
Comprehensive AMR report,: 2022 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, https://www.fda.gov/animal-veterinary/antimicrobial-resistance/2022-summary-report-antimicrobials-sold-or-distributed-use-food-producing-animals
NARMS 2020 Annual Report (published August 2023) – 2020 NARMS Update: Integrated Report Summary | FDA
Draft CVM GFI #283 Priority Zoonotic Animal Drug Designation and Review Process

Draft GFI #273, "Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-273-defining-durations-use-approved-medically-important-antimicrobial-drugs-fed-food

Supporting Antimicrobial Stewardship in Veterinary Settings, Goals for Fiscal Years 2024-2028, https://www.fda.gov/media/172347/download?attachment

FDA-TRACK: Progress on FDA's Support of Antimicrobial Stewardship in Veterinary Settings, https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-progress-fdas-support-antimicrobial-stewardship-veterinary-settings

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.*
- *The Veterinary Innovation Program facilitates advancements in development of innovative animal products by providing greater certainty in the regulatory process, encouraging development and research, and supporting an efficient and predictable pathway to market for animal cells, tissues, and cell- and tissue-based products and intentional genomic alterations in animals. The VIP launched in 2018 as a pilot program. In 2022, the VIP became a permanent program and was expanded to include products pursuing low risk determinations and enforcement discretion as well as products pursuing approval. There are currently 49 products enrolled in the VIP.*
- *LAMP technology, machine learning, and both quasi and culture independent metagenomic methods are under development to support AMR monitoring in water and animal and human food.*
- *CVM is in the process of modernizing our pharmacovigilance software/systems. This is expected to be completed Spring 2023.*

12. Additional comments regarding your report: