WOAH Collaborative Centre Reports Activities 2022

Activities in 2022

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Centre Information

Title of WOAH Collaborating Centre	Veterinary Drug Regulatory Programmes
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Name of the writer:	Dr. Ellen J 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

Training, capacity building	
Title of activity	Scope
	The American Committee for Veterinary Medicines (CAMEVET) is a regional project which aims to facilitate the harmonization of

Committee for Veterinary Medicines of the Americas (CAMEVET), November 9-11th, 2022	standards, records, and control of veterinary medicines among member countries. CVM participated in discussions regarding the harmonization of data requirements regarding antimicrobial resistance in zoonotic pathogens of human health concern and the impact of antimicrobial residues on the human intestinal microbiome. CAMEVET participants requested workshops and trainings regarding CVM's animal drug approval process. XXVII Seminar on harmonization of registration and control of veterinary medicines - Americas (woah.org)
Training, capacity building	
Title of activity	Scope
Question and Answer Session in follow up to the 14th VICH Outreach Forum, Virtual, February 2, 2022	FDA recorded a presentation on the implementation of VICH GLs 6 and 38 on environmental risk assessment, which was shared with participants in the 14th VICH Outreach Forum November 16, 2021. Presenters participated in a follow up webinar the following February to address questions from VICH Outreach Forum Members on the content of the recorded presentation.
Training, capacity building	
Title of activity	Scope
Participated in the 15th VICH Outreach Forum, Virtual, November 15, 2022	The 15th Session of the VICH Outreach Forum was held with in person and virtual participation. CVM provided a presentation on the 9 revised draft VICH GLs on efficacy of anthelmintics. CVM also provided participants for the Outreach Forum pre-meeting discussion on November 14, 2022.
Diagnosis, biotechnology and laboratory	
Title of activity	Scope
CVM's Veterinary Laboratory Investigation and Response Network (Vet-LIRN) Interlaboratory Comparison Exercises	In coordination with other US federal agencies, including other WOAH Collaborating Centers (CDC and USDA), carried out an interlaboratory comparison exercise (ICE) for laboratories testing animal samples for SARS-CoV-2. The specific objectives for this ICE were: (1) to explore the ability of ICE participants, using their routine methods, to positively or negatively detect the presence of SARS-CoV-2 variant(s) in canine nasal matrix; (2) to evaluate specificity of participants' methods by including samples containing RNA from a non-SARS-CoV-2 animal coronavirus.
Diagnosis, biotechnology and laboratory	
Title of activity	Scope
CVM's Veterinary Investigation and Response Network (Vet-LIRN) COVID-19 Grants	Vet-LIRN has also conducted additional work to support COVID-19 testing in animals, including to support new technologies and detection methods with various cooperative agreement grants.
Diagnosis, biotechnology and laboratory	
Title of activity	Scope

Animal Biotechnology Webinar on Low-Risk Intentional Genomic Alterations in Animals for Food Use	The webinar provided information to stakeholders about the agency's risk-based review process for intentional genomic alterations in animals that may pose low risk, as well as revamped web resources for biotechnology products at CVM. The webinar included an overview of the agency's recent determination of low risk for the marketing of products, including food, from two genome-edited beef cattle (PRLR_SLICK Cattle) and their offspring after determining that the intentional genomic alteration does not raise any safety concerns.
Diagnosis, biotechnology and laboratory	
Title of activity	Scope
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 food. Initiated studies to test rivers and streams for AMR genes and bacteria.
Diagnosis, biotechnology and laboratory	
Title of activity	Scope
National Antimicrobial Resistance Monitoring System (NARMS)	FDA initiated a small study to test new methodology for AMR detection in surface waters and the results have been published, https://journals.plos.org/water/article?id=10.1371/journal.pwat.0000067
Veterinary Medicinal Products	
Title of activity	Scope
41st VICH Steering Committee and 15th Outreach Forum, Arlington, VA, USA: November 14-17, 2022	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.
Veterinary Medicinal Products	
Title of activity	Scope
Ad Hoc VeDDRA Meeting, virtual: February 2, 2022, and Annual VeDDRA meeting Virtual: April 26, 2022	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. An Ad Hoc meeting was held to discuss structure and atypical terms which led to a proposal for discussion at the Annual VeDDRA Meeting.
Veterinary Medicinal Products	
Title of activity	Scope

WOAH Electronic Expert Group on Antiparasitic Resistance (EEG APR)	Work with WOAH and other expert group members and serve as group chair to develop guidelines on the responsible and prudent use of antiparasitic products. Activities in 2022 included contributing to the development of several documents outlining potential next steps for the group.
Veterinary Medicinal Products	
Title of activity	Scope
Reviewed new animal drugs for food-producing, companion, and many aquatic animals for possible approval	Review of animal drugs for safety, efficacy, including the safety of any food produced from treated animals.
Veterinary Medicinal Products	
Title of activity	Scope
Development of OECD Test Guideline 320 "Determining Anaerobic Transformation of Chemicals in Liquid Manure"	Participated in the expert group developing this guideline. The guideline was published on June 30, 2022. https://www.oecd.org/chemicalsafety/test-no-320-determining-anaerobic-transformation-of-chemicals-in-liquid-manure-62f5be61-en.htm
Food Safety	
Title of activity	Scope
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 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 preparatory meetings in preparation for the CCRVDF26.
Food Safety	
Title of activity	Scope
Provided leadership and technical expertise to the Codex Alimentarius Commission meeting, Rome, Italy, November & December 2022	Furthered discussion on the Statements of Principle and their application in the adoption of maximum residue limits. Provided background on issues arising from CCRVDF25.
Food Safety	
Title of activity	Scope
Chair OECD Working Party for the Safety of Novel Foods and Feeds	Continue to produce documentation of the standard values for nutrients in plants for comparison to new varieties and represent FDA and USG positions in discussions related to innovative foods and food ingredients
Food Safety	

Title of activity	Scope
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 confidentiality commitment with Ecuador's Vice Ministry of Aquaculture and Fisheries (VMAF). 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/media/161003/download
Food Safety	
Title of activity	Scope
Provided expertise to the Joint FAO/WHO Expert Committee on Food Additives (JECFA), Virtual, May 16-27, 2022	CVM provided technical experts to participate in the JECFA94 meeting, which was held virtually. Experts review veterinary drugs for residue safety and the impact of residues on the human intestinal microbiome, to contribute to the risk assessment requested by the CCRVDF. https://www.who.int/publications/i/item/9789240057586
Food Safety	
Title of activity	Scope
Provided expertise to the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), Rome, Italy, September 12-23, 2022	CVM provided a technical expert to participate in the JMPR meeting, which was held in Italy. 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	
Title of activity	Scope
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.
Feed Safety	
Title of activity	Scope
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)
Zoonoses	

Title of activity	Scope
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.
Veterinary medicinal products	
Title of activity	Scope
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 int 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.
Veterinary medicinal products	
Title of activity	Scope
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.
Veterinary medicinal products	
Title of activity	Scope
WOAH 12th AMU Technical Reference Group	Participate in small (virtual) working group led by WOAH, in providing input for design and future implementation of an electronic platform for WOAH members to submit the antimicrobial consumption (sales or use) country data. A data dashboard is also being developed. CVM contributes one expert to this TRG.
Veterinary medicinal products	
Title of activity	Scope
Transatlantic Task Force on AMR (TATFAR)- various dates throughout 2022	Multiple U.S experts contributed to the work of various TATFAR activities as part of the 2021-2025 work plan.
Veterinary medicinal products	
Title of activity	Scope

EUCAST Subcommittee on AST and ECOFFs	Provide input on how epidemiological cutoff values are established by adding periodic comment to documents created by EUCAST. Provide updates to CLSI on activities in EUCAST as needed.

Veterinary medicinal products	
Title of activity	Scope
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.

Veterinary medicinal products	
Title of activity	Scope
Tripartite/Quadripartite AMR Initiatives	FDA participants provide expert comments to documents related to antimicrobial resistance in the food supply.

Veterinary medicinal products	
Title of activity	Scope
Food and Agriculture Organization (FAO) Regional (Asia) Guideline	Provide technical feedback on draft FAO Regional (Asia) Guideline on surveillance and monitoring of antimicrobial resistance in bacterial pathogens of fish.

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 on antiparasitic resistance (EEG APR)	Work with WOAH and other work group participantsand serve as group chair to develop guidelines on the responsible and prudent use of antiparasitic products, specifically anthelmintics used in food producing ruminant species.	Training and education health management Animal production Veterinary products
Provided leadership to and participated in the 41st VICH Steering Committee and 15th VICH Outreach Forum meeting, Virtual, November 14-17, 2022	Chaired and 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.	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 16 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 Veterinary Drugs Directorate, Health Canada	Held teleconferences and otherwise corresponded throughout the year on topics of mutual interest to both agencies.	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.	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 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

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 OIE 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, Ministry of Agriculture	Japan	Asia and Pasific	Collaborated in the training of veterinary medicine regulatory personnel. Worked together to develop and establish VICH guidelines for the approval and monitoring of veterinary medicines.
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.

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 OIE 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.
Dr. Ellen Hart	Worked with WOAH to help plan March 2022 APR EEG meeting (which was eventually postponed). Worked with WOAH to develop mapping exercise for APR EEG and updated concept note for the group.	The Antiparasitic Resistance Electronic Expert Group (APR EEG) is a co-led by WOAH and FDA/CVM with the goal of providing additional information to member countries and developing guidelines on antiparasitic resistance and the responsible and prudent use of antiparasitic products.
Dr. Anna Obrien	Worked with WOAH to help plan March 2022 APR EEG meeting (which was eventually postponed). Worked with WOAH to develop mapping exercise for APR EEG and updated concept note for the group.	The Antiparasitic Resistance Electronic Expert Group (APR EEG) is a co-led by WOAH and FDA/CVM with the goal of providing additional information to member countries and developing guidelines on antiparasitic resistance and the responsible and prudent use of antiparasitic products.
Dr. Aimee Phillippi-Taylor	Worked with WOAH to help plan March 2022 APR EEG meeting (which was eventually postponed). Worked with WOAH to develop mapping exercise for APR EEG and updated concept note for the group.	The Antiparasitic Resistance Electronic Expert Group (APR EEG) is a co-led by WOAH and FDA/CVM with the goal of providing additional information to member countries and developing guidelines on antiparasitic resistance and the responsible and prudent use of antiparasitic products.
Dr. Katherine 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.
Dr. Stacey Pulver	Assisted with review of species-specific annexes of the List of Antimicrobial Agents of Veterinary Importance and review of WOAH Global Database on Antimicrobial Use.	Development of species-specific annexes of the List of Antimicrobial Agents of Veterinary Importance and review of OIE Global Database on Antimicrobial Use.

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.

Supported WOAH APR EEG – in 2022 helping develop plans for next steps

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 :

b) Seminars : 3

c) Hands-on training courses:

d) Internships (>1 month) :

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 and 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	58
	Part of panel discussion related to the harmonization of data requirements regarding antimicrobial resistance in zoonotic		

B	pathogens of human health concerns and the impact of antimicrobial residues on the human intestinal microbiome at WOAH Committee for Veterinary Medicines of the Americas (CAMEVET), Virtual November 17-19th, 2021.	Americas	200
B	FDA recorded a presentation on the implementation of VICH GLs 6 and 38 on environmental risk assessment, which was shared with participants in the 14th VICH Outreach Forum November 16, 2021. Presenters participated in a follow up webinar on February 2, 2022, to address questions from VICH Outreach Forum Members on the content of the recorded presentation.	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	APR EEG March 2022 Meeting (had to be postponed last minute)	WOAH (Maria Szabo)	2022-03-02	Virtual	0
International	VICH Outreach Forum	VICH	2023-11-14	Hybridl Arlington, VA USA	40

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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Loss, Christopher M., Veterinarians should understand what it means to use conditionally approved drugs, with a focus on conditional approval of companion animal oncology drugs. JAVMA. 2022; online first; 7.25.2022. https://doi.org/10.2460/javma.22.05.0205

Martinez, MN, Papich MG, Fahmy R. Impact of gastrointestinal differences in veterinary species on the oral drug solubility, in vivo

dissolution, and formulation of veterinary therapeutics - PMC (oclc.org). eCollection 2022
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Martinez MN, Wu F, Sinko B, Brayden DJ Grass M, Kesisoglou F, Stewart A, and Sugano K. 2022. A critical overview of the biological effects of excipients (Part II) :Scientific considerations and tools for oral product development. The AAPS Journal 2022. 24(61). https://doi-org.fda.idm.oclc.org/10.1208/s12248-022-00713-1
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Martinez M, Brayden DJ. Spotlight on the Scientific Excellence of Michael John Rathbone, Ph.D. CRS. September 26, 2022. Spotlight on the Scientific Excellence of Michael J. Rathbone, Ph.D. | Controlled Release Society (CRS)
Jelliffe R, Liu J, Drusano GL, and Martinez MN. Commentary: Individualized patient care through model-informed precision dosing: Reflections on training future practitioners. AAPS J 2022. 24:117-129.https://doi.org/10.1208/s12248-022-00769-z
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Miglino AN, Holmes CM. Applying weight of evidence methods to assessing exposure in aquatic environments: Comparing lines of evidence. Integrated Environmental Assessment and Management. Special Series. 7 March 2022. https://doi.org/10.1002/ieam.4602
Pulver S, Chapter 11: Regulation and Authorization of Veterinary Medicines for Sea Lice. IN: Sea Lice Biology and Control. Eds. J Treasurer, I Bricknell and J Bron. 5m Books. ISBN-13 978178918 1913
Aljahdali NH, Khajanchi BK, Weston K, Deck J, Cox J, Singh R, Gilbert J, Sanad YM, Han J, Nayak R, Foley SL. Genotypic and Phenotypic Characterization of Incompatibility Group FIB Positive Salmonella enterica Serovar Typhimurium Isolates from Food Animal Sources. Genes (Basel). 2020 Nov 4;11(11):E1307. doi:10.3390/genes11111307

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Harrison L, Tyson GH, Strain E, Lindsey RL, Strockbine N, Ceric O, Fortenberry GZ, Harris B, Shaw S, Tillman G, Zhao S, Dessai U. Use of Large-Scale Genomics to Identify the Role of Animals and Foods as Potential Sources of Extraintestinal Pathogenic Escherichia coli That Cause Human Illness. Foods. 2022; 11(13):1975. https://doi.org/10.3390/foods11131975
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b) International conferences:
19
European Medical Authority (EMA) Veterinary Big Data Stakeholder Forum, November 23, 2022
- *CVM's use of big data in pharmacovigilance and antimicrobial resistance*

World One Health Congress, November 7-11, 2022
- *NARMS and WGS-based AMR monitoring,*
- *The US National Antimicrobial Resistance Monitoring System: The evolution toward One Health*
- *FDA and USDA Integrated Antimicrobial Resistance Data Dashboards from Companion Animals*

Global Biotechnology Regulators Forum, November 15-16, 2022
- *CVM review of genome-edited SLICK cattle and approval of intentional genomic alteration in GalSafe pigs*
- *CVM's Veterinary Innovation Program*

International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnology, September 12-15, 2022

- *US FDA Country Update*
- *Off target changes, conventional mutation and regulatory approaches for genome editing*

International Feed Regulators Meeting, March 24-25, 2022
- *Moderated ICCF session*

Pharmaceuticals Interest Group – Open Meeting: Global Research & Regulatory Update February 8 and 15, 2022
- *Presented on Steering committee; helped organize global meetings*

Society of Environmental Toxicology and Chemistry (SETAC) Europe Annual Meeting, May 2022
- *Advances in simulating the fate of animal drugs in the US using VETPEC modelling suite*

Africa Food Safety Workshop June 2022
- *Presented on Key Differences in the Procedures for Assigning US Tolerances as Compared to MRLs*

International Association for Food Protection, August 2022
- *Whole-Genome Sequencing Supports Animal Food Compliance and Enforcement Actions*
- *Utilizing the Antibiotic Resistome to Inform the Presence of Antibiotic-Resistant Pathogens in Water*
- *Targeted High Throughput Quasimetagenomic Sequencing Using Hybridization Capture for Detection of Salmonella in an Outbreak Investigation.*

and Drug Administration, Laurel, MD, USA
- *Factors Affecting the Recovery of Low Levels and Isolation of Salmonella enterica from Surface Water: A Multi Laboratory Evaluation of Methods.*
- *Comparative Genomic Analysis of Virulence, Antimicrobial Resistance, and Plasmid Profiles of Salmonella Enteritidis Isolated from Humans in China.*
- *Salmonella serotypes from retail chicken and human infections in the United States, 2002–2018.*

International Conference on Emerging Infectious Disease, August 2022
- *A comparison of Salmonella Serotypes in NARMS Retail Meat (2002-2019) and in Human Clinical Cases (1996-2018)*

c) National conferences:
9
American Veterinary Medical Association (AVMA) Annual Convention
- *Animal Diagnostics and Testing for SARS-CoV-2*
- *Compounding from Bulk Drug Substances*

The Society of Environmental Toxicology and Chemistry (SETAC) North America Annual Meeting, November 13-17
- *Chaired session on analysis of pharmaceuticals in environmental matrices*

Association of Official Agricultural Chemists (AOAC) International Meeting, March 2022
- *Approaches to Safety Assessments for PFAS in Animal Foods*

Swine in Biomedical Research Conference
- *FDA's Oversight of IGAs in Animals*

International Association of Food Protection (IAFP) Annual Meeting
- *FDA's One Health Approach to Mitigating Antimicrobial Resistance Risks*

American Statistical Association (ASA) Biopharmaceutical Section
- *New FDA guidance for innovative approaches in animal drug development*

Parenteral Drug Association (PDA) Pharmaceutical Microbiology Conference
- *The Importance of microbial identification in investigation of deviations*

Metagenomic Insights into Pet Food Microbiomes and Resistomes American Society of Microbiology Next Generation Sequencing

d) Other (Provide website address or link to appropriate information):
33
Revised or published the following 23 Guidance for Industry Documents:
CVM GFI #3 General Principles for Evaluating the Human Food Safety of New Animal Drugs Used In Food-Producing Animals
CVM GFI #90 (VICH GL7) Effectiveness of Anthelmintics: General Recommendations

CVM GFI #95 (VICH GL12) Effectiveness of Anthelmintics: Specific Recommendations for Bovines
CVM GFI #96 (VICH GL13) Effectiveness of Anthelmintics: Specific Recommendations for Ovines
CVM GFI #97 (VICH GL14) Effectiveness of Anthelmintics: Specific Recommendations for Caprines
CVM GFI #100 (VICH GL18 (R2)) Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision 2)
CVM GFI #106 The Use of Published Literature in Support of New Animal Drug Approvals
CVM GFI #108 Registering with CVM's Electronic Submission System
CVM GFI #109 (VICH GL15) Effectiveness of Anthelmintics: Specific Recommendations for Equines
CVM GFI #110 (VICH GL16) Effectiveness of Anthelmintics: Specific Recommendations for Porcines
CVM GFI #111 (VICH GL19) Effectiveness of Anthelmintics: Specific Recommendations for Canines
CVM GFI #113 (VICH GL20) Effectiveness of Anthelmintics: Specific Recommendations for Felines
CVM GFI #114 (VICH GL21) Effectiveness of Anthelmintics: Specific Recommendations for Chickens Gallus gallus
CVM GFI #152 Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern
CVM GFI #159 (VICH GL36) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI
CVM GFI #245 Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
CVM GFI #253 Current Good Manufacturing Practice for Animal Cells, Tissues and Cell- and Tissue-Based Products
CVM GFI #254 Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products
CVM GFI #256 Compounding Animal Drugs from Bulk Drug Substances
CVM GFI #258 Use of Tracers in Animal Food, Type A Medicated Articles, and Medicated Feeds
CVM GFI #272 Practices to Prevent Unsafe Contamination of Animal Feed from Drug Carryover
CVM GFI #276 Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs
Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C Guidance for Industry and FDA Staff
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, June 2022: https://www.fda.gov/media/159544/download
Biomass dashboard went live in November 2022: https://www.fda.gov/animal-veterinary/antimicrobial-resistance/biomass-adjusted-antimicrobial-sales-and-distribution-data-food-producing-animals-interactive
NARMS 2019 Annual Report (published April 2022) – 2019 NARMS Update: Integrated Report Summary | FDA
Evaluation of certain veterinary drug residues in food: ninety-fourth report of the Joint FAO/WHO Expert Committee on Food Additives
XXVII Seminar on harmonization of registration and control of veterinary medicines - Americas (woah.org)
Published Protocols 2022 to contribute to NARMS environmental monitoring initiative:
Backflush of Dead-end Ultrafilter Andrea Ottesen, Brandon Kocurek https://dx.doi.org/10.17504/protocols.io.14egnzp6yg5d/v1
Dead-end Ultrafiltration Water Collection Andrea Ottesen, Brandon Kocurek
https://dx.doi.org/10.17504/protocols.io.q26g78qy9lwz/v1
QIAGEN DNeasy Power Water SOP andrea Ottesen, Brandon Kocurek
https://dx.doi.org/10.17504/protocols.io.rm7vz3wb5gx1/v1

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 metagenomics and LAMP detection methods for the identification of SARS-CoV-2 in animal diagnostic samples.*
- *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: