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Note: Text has been edited for clarity.

21st Century Cures Act – Updates on Implementation

Speakers:

- Patricia Brown, VMD, MS, NIH Office of Laboratory Animal Welfare
- Betty Goldentyer, DVM, USDA APHIS Animal Care
- Brianna Skinner, DVM, MPH, FDA, OCET, Office of the Commissioner

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Slide 1: 21st Century Cures Act – Update on Implementation

>>*Nicolette*: Hello. Today is Thursday, March 11, 2021. I am Nicolette Petervary, part of the Division of Policy and Education at OLAW, and today it is my pleasure to welcome our speakers, Drs. Pat Brown, Betty Goldentyer, and Brianna Skinner to the OLAW Online Seminars to present 21st Century Cures Act: Update on Implementation.

Dr. Pat Brown currently serves as the Director of the Office of Laboratory Animal Welfare. She received her undergraduate degree in Animal Science from the Pennsylvania State University and her veterinary degree from the University of Pennsylvania. She joined the NIH in 1986 serving in several clinical and management positions in the intramural research program before joining OLAW in 2006 as the Director.

Dr. Goldentyer is a graduate of Tufts University School of Veterinary Medicine. She came to USDA after working in a small animal practice and then with a humane society in Chicago. Dr. Goldentyer was an Animal Welfare inspector in Wisconsin, and a Regional Animal Care Specialist before becoming the Regional Director for Animal Care in Raleigh. In July of 2017, she moved to DC to serve as the Associate Deputy Administrator for Animal Care and in December of 2019 became the Deputy Administrator for Animal Care.

Dr. Brianna Skinner is a Commissioned Corps Officer in the U.S. Public Health Service. She is assigned to the Office of Countermeasures and Emerging Threats (OCET) within the Office of the Commissioner at the U.S. Food and Drug Administration (FDA) and serves as a Senior Regulatory Veterinarian. She is an animal model expert for the administration of policies to facilitate the availability of safe and effective medical countermeasures against chemical, biological, radiological, nuclear agents, and emerging threats. Prior to transferring to the FDA, she worked at the Centers for Disease Control and Prevention for over eleven years supporting infectious disease research and consulting with principal investigators on animal care and use in compliance with federal laws and regulations. She is a diplomate in the

American College of Laboratory Animal Medicine and earned her Doctor of Veterinary Medicine degree from Tuskegee University. Her Masters of Public Health was earned from Benedictine University.

Slide 2: 21st Century Cures Act – NIH Actions
It is my pleasure to welcome you to the OLAW Online Seminar and now to hand the microphone over to Pat.

Slide 3: 21st Century Cures Act in a Nutshell
>>*Pat*: Hello, let's start with what is the 21st Century Cures Act in a nutshell? It's comprehensive legislation that was passed back in December 2016. The overall intent of the law is to advance biomedical research from basic research through to advanced clinical trials, and also to streamline the drug and device approval process to bring treatments to patients faster. Next slide.

Slide 4: 21st Century Cures Act in a Nutshell, continued
For our interest today, Section 2034 of the law mandates federal efforts to reduce administrative burden for researchers. Part D of Section 2034 assigns NIH as the lead agency in cooperation with the USDA and FDA to focus on animal care and use in research. Next slide.

Slide 5: What Does 2034(d) Ask?
What does Section 2034(d) specifically ask? It says that not later than 2 years after the law was enacted, the Director of the NIH, in collaboration with the Secretary of Agriculture and the FDA Commissioner, will complete a review of applicable regulations and policies for the care and use of laboratory animals, and make revisions, as appropriate, to reduce administrative burden on investigators, while maintaining the integrity and credibility of research findings and protection of research animals. Next slide.

Slide 6: Working Group Timeline
Following the passage of the law, the NIH convened a Working Group in February 2017. The Working Group was made up of the members of the standing committee that represents the NIH, FDA, and USDA under the memorandum of understanding between the three agencies concerning laboratory animal welfare. At its first meeting, the Working Group decided to start their effort by reviewing relevant regulations and policies. This occurred over the course of 2017.

The Working Group held listening sessions and meetings in 2018 to explain the requirements in the Act, provide updates on the Working Group's progress, and encourage the research community, other stakeholders, and the public to provide their individual ideas for how to meet the requirements of the law.

In March 2018, the Working Group released a request for information (or RFI) for public comment on preliminary suggested actions that the Working Group had identified to improve the coordination and harmonization of the regulations and policies. That RFI received over 19,000 comments.

Based on those responses, the Working Group released a draft report in Dec. 2018 with a 90-day comment period. Based on the further input received from stakeholders about the draft report, the agencies issued the final report in August 2019. Next slide.

Slide 7: 21st Century Curse Act
You can find the final report on the web address listed on this slide. It's on the OLAW website in a page

dedicated to the 21st Century Cures Act. Now I'd like to focus on the progress made by NIH in carrying out the report's proposed actions beginning with guidance and policy updates. Next slide.

Slide 8: NIH Steps: Update Guidance
So where are we in updating OLAW's guidance and policies? OLAW has developed updated guidance on three of the action items for NIH identified in the Working Group's report on reducing burden. These three proposed changes were available for public comment in the summer and fall of 2020 and were announced through Notices in the NIH Guide for Grants and Contracts.

- The most recent of these presented proposed changes [is] in the instructions to the domestic Animal Welfare Assurance to support the use of AAALAC Program Description elements. This RFI [NOT-OD-20-169] asked for responses to consider whether select elements of the AAALAC Program Description are relevant to the associated part of the OLAW Assurance and identify any concerns.

- The next notice [NOT-OD-20-153] sought input on OLAW's proposed clarifying guidance regarding the institutional responsibility to ensure that the research described in NIH grant applications and contract proposals is congruent with corresponding protocols approved by the IACUC. This proposed clarifying guidance was coordinated with the NIH Office for Policy on Extramural Research Administration, the office that oversees NIH grants policy.

- And the third notice [NOT-OD-20-145] asked for input on 10 identified flexibilities available for conducting semiannual animal facility inspections. Because this guidance impacts both OLAW- and USDA- overseen institutions, USDA has reviewed and concurs with the proposed guidance.

In summary, final guidance on all 3 of these policies are expected this spring, 2021. Next slide.

Slide 9: NIH Steps: Update guidance, continued
OLAW is working on but has yet to release proposed guidance and resources on the following topics that were identified for NIH action in the report. This includes:

- expanded use of Designated Member Review for protocol review and use of Veterinary Verification and Consultation for certain significant changes to approved protocols, also

- what is exempt from IACUC review

- the options for IACUC review of non-pharmaceutical grade substances

- noncompliance reporting requirements for what is reportable to OLAW, what not to report, and what to include in the report

- and lastly, clarifying the requirements for IACUC's to report departures from the *Guide* in the semiannual report to the Institutional Official

- and lastly, applicability of the PHS Policy to zebrafish immediately after hatching.

I'd like to acknowledge the diligent efforts of OLAW's Division of Policy and Education in developing this new guidance and associated resources, and the guidance that is in ongoing development. Next slide.

Slide 10: NIH Steps to Improve Coordination
The 21st Century Cures Act also requires the agencies to improve coordination of regulations and

policies. Displayed here are the coordination steps that NIH is undertaking and the progress that has been made on each.

- In blue on the slide, was the plan for OLAW to harmonize with USDA to allow institutions to submit annual reports to both agencies by December 1 each year. This reporting schedule is now in place and was effective for the 2020 OLAW Annual Report.
- In green on the slide is our proposed change in the instructions to the domestic Animal Welfare Assurance to support the use of the AAALAC Program Description elements, as I've already described. We expect to have the final guidance released in the spring on this topic.
- In purple we have implemented a minimum of 60 days for comments on proposed policy and guidance changes. An example is the 60-day comment period on the 2020 update to the AVMA Guidelines for the Euthanasia of Animals, and our three 2020 Requests for Information, that all allowed a 90-day comment period due to the pandemic.
- In red is a proposed update to OLAW's disclaimer on issued policy guidance. This has not yet been undertaken due to the change in the administration and pending guidance on whether agencies are to implement former President Trump's Executive Order 13891, and the related Office of Management and Budget memorandum on the use of guidance documents to clarify existing or new regulations. Next slide.

Slide 11: More NIH Steps to Improve Coordination
Here are some other coordination activities that are ongoing:

- We have included the Department of Defense and the Veterans Administration in meetings with OLAW, USDA, and FDA to discuss harmonization efforts. As a result, both agencies are making refinements to their policies to better align with Animal Welfare Act and PHS Policy requirements. These agencies are also participating in the new initiatives of the Federal Demonstration Partnership that I will discuss later.
- Through our support for the educational activities of the ICARE Project, IACUC 101, the Scientists Center for Animal Welfare, PRIM&R, and the IACUC Administrators Association, OLAW is actively engaged in supporting the continued development of training to assist IACUC members, IACUC administrators, and institutional leadership in reducing self-imposed administrative burden on investigators.
- In addition, Dr. Axel Wolff, OLAW's Deputy Director, serves as the cochair of the Animal Care and Use Subcommittee of the Federal Demonstration Partnership. The FDP is supporting the creation of the Compliance Unit Standard Procedure repository (known as CUSP) that will contain standard procedures used for research with animals.
- OLAW, along with USDA, VA, and DOD, are also involved with the efforts of the IACUC Administrators Association and the Federal Demonstration Partnership to develop a universal IACUC protocol template.
- OLAW plans to continue our support and engagement with the IACUC Administrators Association to provide resources to IACUCs to integrate common practices into their institutional processes, to continue to reduce administrative burden on investigators.

- As part of our release of new guidance or when we are clarifying existing guidance, we are adding new resources to the OLAW website to assist IACUCs and researchers in understanding the flexibilities in the PHS Policy for the oversight and conduct of research with animals. Examples of these include:
    - A webpage with Questions and Answers on implementation of the 2020 AVMA Euthanasia Guidelines
    - A webpage on COVID-19 Pandemic Contingency Planning for Animal Care and Use Programs with links to three webinar recordings and over 20 Frequently Asked Questions for IACUCs and Animal Facilities on pandemic-related topics, and
    - An updated webpage on the Annual Report to OLAW.

Next slide.

Slide 12: 21st Century Cures Act USDA APHIS Actions
And now I'm going to turn this over to Betty to talk about USDA's proposed actions. Welcome Betty.

Slide 13: USDA Steps to Reduce Burden
>> Betty: Thanks, Pat. Let's go ahead and get started right away with the proposed rule that USDA published in the Federal Register last September**.** This Rule change is intended to address reforms called for in the Cures Act, namely, to identify inconsistent, overlapping, or unnecessarily duplicative regulations and policies and also streamline regulations that unnecessarily impose administrative burdens or costs on regulated entities.

The changes address 3 areas:

1. facility registration renewals
2. continuing reviews of activities or protocols at appropriate intervals but not less than annually, and
3. the annual report and signature requirement for the annual report.

We got 61 comments on the proposed rule in the 60 days it was open for comment, and we do appreciate those comments. They are always very substantive and helpful to us as we move to the final rule.

Slide 14: USDA Steps to Reduce Burden: Proposed Rule
So, starting with the protocol review proposal and the current requirement is to conduct continuing reviews of activities not less than annually. We proposed removing that requirement, and instead inserting a requirement that IACUCs conduct a three-year complete review of activities. It's important to note that the IACUCs would continue to review and approve significant changes regarding the care and use of animals in ongoing protocols, and that the IACUC may always choose to review a protocol at an interval more frequently than three years as part of their program review. This change would align USDA and NIH requirements and would reduce the time and effort dedicated to reviewing protocols on an annual basis, while retaining the benefits of a thorough complete review every three years and ongoing review of any significant changes. I know many of you are already conducting a complete review every three years, but we see a real benefit to animal welfare by replacing what can sometimes be a pro forma annual review with this complete three-year review.

Slide 15: USDA Steps to Reduce Burden: Proposed Rule
Now, the second part of the proposal would be to eliminate the requirement for the Chief Executive Officer (CEO) and the Institutional Official to sign the Annual Report. This helps us move away from paper forms and go electronic. Removing the signature requirement guards against identity theft and allows the facility representative to electronically submit the annual report on behalf of the CEO or IO while maintaining the requirements for the facility annual report and practices. And just a note on this, year by year, more and more of you are filing electronically, which is great. Six hundred this year of our roughly eleven hundred submissions were submitted through the online system.

Slide 16: USDA Steps to Reduce Burden, Proposed Rule (continued)
The last piece of the proposed regulation, 2.30, proposes to eliminate the need to renew the registration every three years. So currently, you renew every 3 years, and this would eliminate that need. We are proposing adding a little information onto the annual report, and then the annual report will take care of any updates we need, so no registration renewal would be required. You just register once, file your annual reports, and that would be the end of it. We will also be removing the language in the regulations about inactive status. It's so easy to get a new registration that there's really no need for that inactive status, and so this is cleaning up a regulation that has not been used in years. Facilities will either be registered with us or not registered with us.

Slide 17: Awaiting Departmental clearance to publish a Final Rule
And where we are with this rule? Awaiting departmental clearance. As Pat mentioned, we have a new administration, and they're going to be taking a look at this proposed rule that we have and making sure everything is in line with their priorities. If all goes well, the next step would be publication of a final rule, and in the final rule there will be an effective date.

Slide 18: Steps to Reduce Burden: Flexibilities
Now on to some other ways to reduce burden. As Pat mentioned, we want to increase flexibilities and make sure we have good guidance available, particularly with regard to the semiannual facility inspections. So, use of the AALAC site visit is one of the semiannual flexibilities that you have. We've also been looking at virtual inspections, that have been really helpful over the last year.

We want to make the most efficient use of our IACUC members during the semiannual facility inspections. There is no need for two members to be together in every single room and it can be very efficient also to use consultants when possible.

So, we're working now to get information out on all of those flexibilities.

Slide 19: Steps to Reduce Burden: Reporting
So, for reporting, I did talk a little bit about the online portal. And as Pat mentioned, we are now on the same reporting schedule and will be exploring the development of a single portal to make it even easier for everyone.

Slide 20: USDA Steps to Reduce Burden: Guidance
On guidance:

- Significant new policies and any revision to policies will be made available for public comment, and we will always have a statement in our guidance documents to explain that they are clarifications, and are not legally binding like regulations.

- An example of this is the proposed policy on research involving free-living wild animals in their natural habitat and field studies, which we published for comment. We took comments on that in September and October. The comments have been reviewed and that final guidance is also in the clearance process.

Slide 21: 21st Century Cures Act FDA Actions
>>*Betty:* And with that I will hand it over to Brianna.

Slide 22: FDA Steps to Reduce Burden
>>*Brianna*: Thank you Betty and thank you for the opportunity to discuss how FDA is reducing regulatory burden according to the 21st Century Cures Act.

FDA's steps to reduce burden in respect to FDA's rulemaking to part 58 of the Good Laboratory Practices for Nonclinical Laboratory Studies are still ongoing. Any comments made in response to the 21st Century Cures Act during the request for information regarding the subject of the GLP rulemaking is still being taken under advisement as the finalization of the proposed rule is considered. Some changes with the proposed rules and guidances involve modifying definitions and terms, as well as including additional regulatory activities that were not included previously, such as the regulation with tobacco. Next slide please.

Slide 23: FDA Steps to Reduce Burden, continued
So, NIH OLAW, in consultation with FDA, plans to review and update the guidance on non-pharmaceutical grade compounds to further clarify options, so IACUCs can review, just as mentioned previously. Next slide.

Slide 24: FDA Steps to Reduce Burden, continued
Now I'm going to talk about guidance for industry put out recently related to compounded drugs. This was put out by FDA's Center for Veterinary Medicine, and I'm going to give a little background. The Food, Drug and Cosmetic Act (FD&C Act) gives FDA the authority to regulate new animal drugs, which includes animal drugs compounded from bulk drug substances. The FD&C Act does not differentiate based on how and where the animal drug is produced to determine the scope of FDA's authority over pre-market approval and other requirements for animal drugs. When Congress amended the FD&C Act (via the Food and Drug Administration Modernization Act [FDAMA] in 1997, as well as the Drug Quality and Security Act [DQSA] of 2013), it addressed provisions for compounding of human drugs, but it exempted those drugs under certain circumstances from the requirements for pre-market approval, Good Manufacturing Practices (GMPs), and adequate directions for use. These provisions are structured as exemptions from requirements because otherwise the requirements would apply. Only compounded human drugs can qualify for these exemptions. Next slide please.

Slide 25: FDA Steps to Reduce Burden, continued
So, a compounded animal drug is made by combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual animal or group of animals. These drugs, which can play a critical role in veterinary medicine, are typically made by pharmacists or veterinarians.

Compounded animal drugs are not FDA-approved. When FDA approves an animal drug, the approval covers a finished drug product, complete with specific active and inactive ingredients, manufactured and labeled in a particular way, and ready for use by a veterinarian or patient without further

manufacturing. So, FDA approval means that FDA has reviewed data demonstrating the animal drug is safe, effective, quality manufactured, and there is truth in the labelling. Further, the approved animal drug becomes part of a post-approval pharmacovigilance program, where there is monitoring of adverse events, product defects, advertising, and manufacturing and labeling changes for the approved animal drug. Because compounded drugs are not FDA-approved, they do not have the same assurances of safety, effectiveness, and quality as approved animal drugs. Next slide please.

Slide 26: FDA Steps to Reduce Burden, continued

Nevertheless, these compounded drugs are important in veterinary medicine because veterinarians treat a wide variety of animal species with a wide variety of conditions, and there aren't always approved drugs that can be used. In those situations, veterinarians may turn to a compounded animal drug to provide treatment. Sometimes, the drug is compounded using an approved animal drug as the source of the compounded drug's active ingredient. In other cases, the drug is compounded using a bulk drug substance, such as a raw pharmaceutical ingredient, that becomes the active ingredient in the compounded drug. When an approved animal drug is used to compound another animal drug, there is greater assurance that the active ingredient is of sufficient quality because it has been evaluated as part of the approval, compared to an animal drug compounded from a bulk drug substance that has not been evaluated.

The Food Drug and Cosmetic Act permits compounding of animal drugs when the source of the active ingredient is a finished, FDA-approved drug. However, in contrast, animal drugs compounded from bulk drug substances are not lawful under the Act. Nevertheless, there are situations in which a needed compounded animal drug can only be made using a bulk drug substance.

Animal drug compounding is a priority for FDA's Center for Veterinary Medicine (CVM), where the mission is "protecting human and animal health." Compounding from bulk drug substances is a significant animal health concern because these drugs, and their active pharmaceutical ingredients, have not been evaluated for animal safety, effectiveness, human user safety, or human food safety. Certain compounded animal drugs may present safety concerns for the person administering the drug or to people who are in contact with a treated animal. There have been cases of bulk drug substance-compounded products causing illness and death in animals due to inappropriate levels of an active ingredient in, or bacterial or fungal contamination of, the product. The Center for Veterinary Medicine at FDA believes that the animal drug approval process protects human and animal health by making available animal drugs of proven safety, effectiveness, and quality, but also acknowledges that there are circumstances in which the only appropriate treatment option for an animal is a drug compounded from bulk drug substance. Next slide please.

Slide 27: FDA Steps to Reduce Burden, continued

To balance these concerns, on November 19, 2019, the Center for Veterinary Medicine issued draft Guidance for Industry #256, titled "Compounding Animal Drugs from Bulk Drug Substances." The draft guidance, if finalized, would describe our animal drug compounding enforcement priorities and advise veterinarians, pharmacists, and the public on circumstances under which FDA does not intend to take action for certain violations of the Food, Drug &Cosmetic Act when pharmacists and veterinarians compound or oversee the compounding of animal drugs from a bulk drug substance. Next slide please.

Slide 28: FDA Steps to Reduce Burden, continued
What FDA is most concerned about with compounded drugs are four factors. The first two are in this slide, which are:

1. bulk substances that present human or animal safety concerns, and
2. those used in food animals.

Next slide, please.

Slide 29: FDA Steps to Reduce Burden, continued
They [FDA] are also concerned with copies of approved, conditionally approved, or indexed marketed animal drugs. And if the drugs are compounded using a patient-specific prescription. Next slide, please.

Slide 30: FDA Steps to Reduce Burden, continued
So if the draft guidance is finalized without significant changes, veterinarians would be able to write patient-specific prescriptions for animal drugs compounded from bulk drug substances for non-food-producing animals as long as, among other things:

1. the patient or group of patients is identified on the prescription, and
2. the compounded drug is not a copy of an FDA-approved product.

Next slide, please.

Slide 31: FDA Steps to Reduce Burden, continued
The draft guidance would also establish a list of bulk drug substances that can be used to compound office stock veterinarians need to have on hand for emergencies to treat non-food-producing animals, or antidotes for food-producing animals. But this list does not apply to compounding from bulk drug substances for patient-specific prescriptions.

Next slide, please.

Slide 32: FDA Steps to Reduce Burden, continued
When the proposal for the Guidance for Industry # 256 was made public, the Center for Veterinary Medicine at FDA received over 1,400 comments. CVM is currently reviewing those comments, which includes submissions from the American Association of Laboratory Animal Science as well as the Office of Laboratory Animal Welfare.

Slide 33: 21st Century Cures Act Implementation Summary
So, in summary, you can see that the three agencies are making progress on the actions described in the report and will identify additional areas to protect animal welfare while reducing unnecessary burden on researchers. Opportunities for public comment will be offered as we continue to develop our new guidance and policy. We intend to evaluate the outcome of the efforts to reduce administrative burden while maintaining scientific integrity and animal welfare. And that's all I have, thank you.

Slide 34: OLAW Q&A – Question 1
>>*Nicolette*: Thank you Brianna. Now, we'd like to address a few questions we received from stakeholders before the webinar. The first question is for OLAW, and it states:

How will you engage with stakeholders while implementing 21 CCA action items?

Slide 35: OLAW Q&A – Answer to Question 1
>>*Pat:* As we have with the development of the report itself, the three agencies will continue to offer the public a comment period as new policies and new guidance are announced. The comments are very important in helping us shape the final versions of the policies and the guidance that we develop.

Slide 36: OLAW Q&A – Question 2
>>*Nicolette*: Thank you, Pat. This next question is for USDA. When can we stop conducting the annual continuing reviews?

Slide 37: OLAW Q&A – Answer to Question 2
>>*Betty*: So, not yet. This is a regulatory change, or it will be a regulatory change, and that just takes time. The process includes the proposed rule for public comment, and the review of the comments, and then any necessary adjustments, and then once a final rule is published with an effective date, that's when the new regulation will be in effect.

Slide 38: OLAW Q&A – Question 3
>>*Nicolette*: Thank you Betty. Here is another question for USDA. What is the status of the USDA Animal Care Policy Manual revision and opportunity for public comment?

Since the delays have been so extensive, leaving animals vulnerable, would USDA consider a more prudent and practical process? Namely, might it conduct a review of each policy while the other policies remain in place?

Slide 39: OLAW Q&A – Answer to Question 3
>>*Betty*: We are going to be moving very deliberately and transparently, reviewing any policies and technical notes and giving an opportunity to comment, like the example with the wildlife studies that I gave earlier. Once we've completed reviewing all the comments, and make sure there is no added burden or regulatory overreach, then we'll post them as they are approved. Some of the previous policies we have found are no longer needed and probably won't come back, but we do recognize that some of those topics that we had in the policy manual were helpful and we're going to be working through those.

Slide 40: OLAW Q&A – Question 4
>>*Nicolette*: Thank you Betty. Here is a general question for the Working Group. How do you intend to evaluate the Working Group's ongoing efforts to reduce administrative burden?

Slide 41: OLAW Q&A – Answer to Question 4
>>*Pat:* I'll take this one. The plan is to enlist an evaluation team to gather input from researchers, IACUC members, and animal care and use program representatives. Our plan is to engage with key representatives from scientific and professional organizations and use their leverage with their constituents to develop and distribute the surveys and gather information on the effectiveness of the agencies actions in reducing the administrative burden on researchers.

Slide 42: OLAW Q&A – Question 5
>>*Nicolette:* Thank you Pat. Here is another general question for the Working Group. How will the process to reduce regulatory burden ensure that animal welfare best practices will never be at the expense of reducing administrative burden or political expediency?

Slide 43: OLAW Q&A – Answer to Question 5
>>Pat: The Working Group from the very beginning of this effort has always made the top priority animal welfare. We will continue to keep animal welfare at the most important place it needs to be, which is at the top of the list.

Slide 44: OLAW Q&A – Question 6
>>*Nicolette*: Thank you Pat. Now we have a few questions for FDA. At what stage are the GLP rules under review? And when will the next version of the GLP rules be available for review by the public? Brianna?

Slide 45: OLAW Q&A – Answer to Question 6
>>Brianna: FDA is still reviewing comments to the proposed rulemaking. FDA will coordinate with NIH and USDA as per our memorandum of understanding for the final clearance before the final rule is published.

Slide 46: OLAW Q&A – Question 7
>>Nicolette: Thank you Brianna. Here is another question for the FDA. What act gives the FDA the statutory authority to regulate new animal drugs?

Slide 47: OLAW Q&A – Answer to Question 7
>>Brianna: The Federal Food, Drug and Cosmetic Act (FD&C Act) gives FDA the authority to regulate new animal drugs, which includes animal drugs compounded from bulk drug substances, as we discussed with the new draft guidance for industry that was put out by the Center for Veterinary Medicine.

Slide 48: OLAW Q&A – Question 8
>>Nicolette: Thank you Brianna. One last question for the FDA: What draft guidance, if finalized, would describe the FDA's animal drug compounding enforcement priorities?

Slide 49: OLAW Q&A – Answer to Question 8
>>Brianna: The draft Guidance for Industry #256, which is titled "Compounding Animal Drugs from Bulk Drug Substances," if finalized, would describe FDA's animal drug compounding enforcement priorities and it would also advise veterinarians, pharmacists, and the public on circumstances under which FDA does not intend to take action for certain violations of the FD&C Act.

Slide 50: 21st Century Cures Act – Update on Implementation
>>Nicolette: Thank you Brianna. We have come to the end of the questions that were sent in advance of the webinar. Thank you for these interesting questions on an important topic. If listeners think of additional questions in the next week, please send them in to us and we will ask Pat, Betty, and Brianna to answer them, and then amend them to the end of the transcript, which we will be posting on the OLAW website.

My thanks to all of you – Pat, Betty, and Brianna, and especially our participants. You have been incredibly generous with your time.

Slide 51: Next OLAW Webinar
>>Nicolette: We look forward to meeting you again at our next webinar, to be held in June 2021. Thank you and goodbye.

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