

Forfa, Tracey

From: Flynn, William T
Sent: Thursday, May 26, 2011 1:39 PM
To: Dunham, Bernadette M; CVM Center Executive Board
Subject: RE: NRDC Files Lawsuit

I find this response from AHI to be very problematic. They make no reference to the fact that they are working with FDA to address this issue. They simply refer to the fact that the risk is "vanishingly small" and that the products are approved by FDA and are therefore safe (i.e., there is no problem). This type of position just reinforces the idea that legislation (or perhaps a lawsuit) is needed because FDA's plan to work with industry will not work.

I think we should consider reminding AHI of this point.

Bill

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From: Dunham, Bernadette M
Sent: Thursday, May 26, 2011 12:19 PM
To: CVM Center Executive Board
Subject: Fw: NRDC Files Lawsuit

FYI
 Cheers,
 Bernadette

Bernadette Dunham, D.V.M., Ph.D. (sent via BB)
 Director, Center for Veterinary Medicine
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 7519 Standish Place, MPN-IV, Rm. 181
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 Leadership. Innovation. Excellence.

From: Alexander S. Mathews [<mailto:amathews@AHI.ORG>]
Sent: Thursday, May 26, 2011 12:17 PM
To: Dunham, Bernadette M
Subject: Re: NRDC Files Lawsuit

Hi Bernadette,

This is what we're saying to the trade press. Just FYI. Have a great weekend -- again!

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5/27/2011

We've consistently said that policy decisions about the use of antibiotics in animals should be made on the basis of careful scientific risk assessment. Several risk assessments measuring the risk of various antibiotic compounds used in animal agriculture have been published in peer reviewed journals, and they uniformly find the risk to public health to be vanishingly small. In one example, the risk of a human antibiotic treatment failure due to the use of an antibiotic in animals was less than that of dying from a bee sting.

The lawsuit not only ignores this recent science, but also fails to cite any data or new information.

Antibiotics used to keep food animals healthy have been approved by FDA as safe and effective. Recent scientific studies have documented the benefits of carefully using antibiotics to keep food animals healthy, because healthy animals produce safer meat products.

On May 26, 2011, at 7:40 AM, "Dunham, Bernadette M" <Bernadette.Dunham@fda.hhs.gov> wrote:

Have a wonderful Memorial Day Weekend!!

Cheers,
Bernadette

Bernadette Dunham, D.V.M., Ph.D. (sent via BB)
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From: Alexander S. Mathews [<mailto:amathews@AHI.ORG>]
Sent: Thursday, May 26, 2011 07:21 AM
To: Dunham, Bernadette M
Subject: Re: NRDC Files Lawsuit

Hi Bernadette,

I did see it and we're going through it now.

Many thanks.

Alex

On May 25, 2011, at 11:57 PM, "Dunham, Bernadette M" <Bernadette.Dunham@fda.hhs.gov> wrote:

Hello Alex,

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Dangin, Alfian

From: Steinberg, Nadine
Sent: Thursday, December 01, 2011 1:11 PM
To: Flynn, William T; Cosgrove, Thomas
Subject: RE: NOOH withdrawal

Bill/Tom:

This is what we said in the CP responses, and is currently in the FR notice withdrawing the NOOHs. I think we can address Mike's request with a few very simple tweaks. These tweaks are in red, embedded in the original language. What do you think?

FDA intends to work with sponsors who approach FDA and are interested in working cooperatively with the Agency to phase out production uses of medically important antimicrobials and to achieve an orderly transition of medically important antimicrobials currently approved for over the counter use in food-producing animals to a marketing status that involves veterinary oversight (i.e., veterinary feed directive ("VFD") status for feed use drugs and prescription status for drugs approved for use through other routes of administration).

From: Flynn, William T
Sent: Thursday, December 01, 2011 12:38 PM
To: Steinberg, Nadine; Cosgrove, Thomas
Subject: NOOH withdrawal

Nadine and Tom,

I received a message from Caitlin Boon that Mike has reviewed the NOOH withdrawal notice and is generally OK with it. One request he did have was to try to incorporate some language about the idea that one of the elements of our strategy is to provide for an orderly phase out of production uses of the medically important drugs. I am not sure whether we had mentioned this in the CP responses but perhaps there is some language we could lift.

Thanks
Bill

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