Sheppard, Reginald D - APHIS Nov 7 (4 days ago)
to me

Forward To: Bundy, Mildred O - APHIS; Coyle, Bonnie M - APHIS
Cc: Vagnoni, Katherine E - APHIS; Boyd, Shirley A - APHIS; McCain, Ke Wanda L - APHIS
Subject: RE: FYI !

Good Afternoon Mr. Hines.

Below is a list questions and some information regarding the subject(s) of your request. Please take the time and review and answer the questions. I am currently out of the office, so you are more than welcome to send your response to me sometime next week. Thank you for your service to our country and enjoy Veterans' Day.

Here is a list of questions and also general information regarding FOIA request 14-0205.

<u>FOIA 14-0205</u>

The requestor states, "I would also like to receive copies of the initial trial data submitted to the USDA and on whose basis, these vaccines were granted USDA approval."

There are several studies that are performed in the process of licensing a veterinary biologic. Which studies would you want copies of?

Also, when a veterinary vaccine contains multiple antigens the number of studies increases. Are you requesting the studies for each fraction or are you requesting the studies performed to evaluate the Leptospirosis strain in the products?

Many of the studies performed for the Leptospirosis antigens were conducted prior to 1996. The Center for Veterinary Biologics (CVB) no longer has records for studies performed prior to 1996.

All study records maintained at CVB contain Confidential Business Information (CBI) and information that would be considered trade secrets that the manufacturers would not want provided to competitors. The manufacturers own the records that the CVB maintains for the licensure of veterinary biologics. These records would be provided to the respective manufacturer for redaction of the CBI and/or trade secret information prior to the records being provided to you.

The FOIA request lists 7 product trade names, which are in parenthesis below. I have listed the Establishment that manufactures the product and the respective Product Code assigned by CVB when the product was licensed. I also included the year when the Leptospirosis studies were approved by CVB, to identify if the records are available at CVB.

1. (Recombitek 4 Lepto) Merial Inc., Est. 298, Code 2668.00; First Licensed 18 Feb 2010 and label claims approved 2007.

2. (Canine 1-DAPPv+L4) Merck Animal Health, Est. 165A, Code 47K1.20; First Licensed 29 July 2010 and label claims approved in 2008, 2009 & 2010. Combination product of Codes 13D1.20 & 2668.00.

3. (Solo-Jec 7 Plus) Boehringer Ingelheim Vetmedica, Inc., Est. 124, Codes 46J8.20; First licensed 22 Jan 2008 and Lepto

label claims all approved prior to 1996, study records are not available.

4. (Duramune Max 5/4L) Boehringer Ingelheim Vetmedica, Inc., Est. 124, Code 4637.29; First licensed 10 Jun 2011 as part of buyout of Est. 112, Code 4637.29. Lepto label claims all approved prior to 1996, study records are not available.

5. (Vangard Plus 5 L4) Pfizer Animal Health, Est. 189, & Zoetis Inc., Est. 190, Code 47K1.20; Est. 189 Code First Licensed 28 Jun 2005, breakout based on Code 47L9.20. Label claims all approved prior to 1996, records are not available. Est. 190 Code First Licensed 28 March 2013 from buyout of Est. 189.

6. (Vangard Plus 5 L4) Zoetis Inc., Est. 190, Code 47L9.20; First Licensed 28 Mar 2013 from buyout of Est. 189, Code 47L9.20. Label claims all approved prior to 1996, records are not available.

7. (Spectra 7) Boehringer Ingelheim Vetmedica, Inc., Est. 124, Code 46J8.20; First Licensed 22 Jan 2008. Lepto label claims all approved prior to 1996, records are not available.

8. (Univac 7) Boehringer Ingelheim Vetmedica, Inc., Est. 124, Code 46J8.20 (Same product information as above.) Trade name used by different distributors for the same product.

CVB does not have this study data/information publicly available at this time. Making this information available is part of a label regulation change that is in process. CVB is not able to provide estimation on when the regulation change will be approved and in place.

Bonnie M. Coyle, Section Leader
Program Information Management and Security (PIMS)
Center for Veterinary Biologics, Inspection and Compliance
USDA, APHIS, Veterinary Services
1920 Dayton Avenue
Ames, Iowa 50010

Phone: (515) 337-6561
Fax: (515) 337-6120
email: bonnie.m.coyle@aphis.usda.gov

1:51 PM (9 minutes ago)

to Reginald

Nov 12

Dear Mr. Sheppard,

Thank you for your most recent emails

1) I am requesting studies performed to evaluate the leptospirosis protection afforded to dogs that were submitted to the CVB when the products were considered for approval by the CVB. We can limit that to Merial Inc. Recombitek 4Lepto Est. 298,Code 2668.00 and Merck Animal Health Canine 1-DAPPv+L4 Est. 165A, Code 47K1.20

2) I am requesting to be informed of the number of adverse reaction/adverse effect reports or other dog-owner complaints related to the vaccines that were submitted to the CVB or to vaccine manufacturers who subsequently forwarded those reports to the CVB in 2011, 2012 and 2013 and a breakdown of which of your 7 manufacturer's products they pertained to. I assume they are already filed accoring to product manufacturer.

Since I am not requesting any information as to the constituents and formulations of the vaccines, which, I understand are proprietary, I see no need for my request to the CVB to be reviewed or approved by the vaccine manufacturers themselves. These are clearly legitimate queries to be answered under the Freedom Of Information Act.

Sincerely,

Ron Hines

Good Day Mr. Hines! .....Nov 13

The program has a follow up question (see below):

You're asking for the listing of the studies performed or the study data for the studies performed to evaluate the leptospirosis protection? Those are two completely different items. Your initial request said study data but in the follow-up he asked for the studies performed.

Dear Mr. Sheppard, ...Nov 13

I would prefer that the CVB not play word games with me. You know that knowing what studies were performed without knowing the results of those studies would be of no value to me. Do you plan to use the same tactics to deny me access to the adverse event reports?

Sincerely,

Ron Hines