EF

Minutes of Meeting Held on Wednesday, March 8, 2006, at the Chicago District office, beginning at 2:30pm, between:

FDA representatives: Scott J. MacIntire, District Director; Richard Harrison, Compliance Director; and, Dorothy S. Stanback, Import Compliance Officer,

And

PetAg representatives: George Gill, President and CEO; and, Barbara Roedel, Regulatory Manager.

Mr. MacIntire thanked the representatives from PetAg for attending the meeting. Mr. Gill said his firm's business is focused on neo-pets. His said the zoologic line of products is approved for use by the agency in charge of endangered species. He said his firm was originally a part of Borden. He indicated his firm has no domestic supplier at present. He said the foreman was fired – due to issues related to the salmonella contaminated rawhide products. He said his firm had sent their products to be radiated. Their first lab, he said, was not fully compliant with BAM and the firm then switched to (b) (4) . That sampling was still out of line and now they have submitted to FDA the results of the third sampling. He said they would like to obtain release of the products and that they would place the radiation symbol on the product.

Richard Harrison provided to everyone present the latest list of questions from the FDA laboratory.

Mr. MacIntire said that FDA's sampling of the product was scientifically based. He said the industry may have their own sampling guidelines. He said FDA needs assurance that the sampling conducted by PetAg or their private lab was truly representative.

Ms. Stanback said there was sampling guidance on the Internet – FDA's website.

Ms. Roedel said that (b) (4) is on point and has experience in doing this type of sampling and salmonella analysis.

Mr. Gill said they would start getting answers from (b) (4) today.

Mr. MacIntire asked the representatives why rawhide was obtained from foreign rather than domestic suppliers.

Mr. Gill said that they are cheaper from overseas. Currently, US hides are exported to (b) (4) split there, then shipped to (b) (4) for labor cost reasons.

Mr. Macintire said that globally marketed products require better control of quality. He said the firm would have to pay close attention to entities that supply them with raw materials. He said the firm needed to establish good controls at the foreign supplier sites.

Ms. Stantack reminded everyone that the sampling conducted late in 2004 was positive for salmonella and that this generated an FDA Import Alert.

Ms. Roedel said that (b) (4) testing was detailed as prepared by (b) (4) and as submitted on the 766. (b) (4) said the (b) (4) protocols were submitted.

Mr. Gill asked that assuming that we get a prompt response how long before release would occur.

Ms. Stanback said to send the answers to the questions to her via email.

Mr. Gill said that we know there is a radiation symbol required, but that competitors are not placing them on their products where they should be. The "header" might be too busy on the PetAg labels for the radiation symbol to go there. He asked if it would be possible to place the symbol else where on the label or on the back or side of the product rather than the label panel itself.

Mr. Harrison asked the firm to email or fax a label specimen to the district for review.

Ms. Stanback pointed out the label would also require net content information.

Mr. Gill said that it would be corrected. He thanked the district representatives for their time.

Mr. MacIntire thanked both Mr. Gill and Ms. Roedel for coming in.

Richard Harrison
Compliance Director
Chicago District

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