

Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
Sent: 6/5/2018 12:36:50 AM
To: Stratton Edwards [sedwards@capitolhillcg.com]
CC: Mike Ruley [mruley@alliedbioscience.com]; Weiss, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ce04987a3784f21985f65e96c220b84-Weiss, Steven]; Keller, Kaitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a6b15adfd745c6ada1c121dec27ac4-Keller, Kai]
Subject: RE: Follow up to Allied BioScience meeting

Stratton,

I'm happy to provide some clarifications for you.

For the categories of claims in hospital settings and the appropriate category for your product, we discussed the current processes for getting hospital acquired infection (HAI) claims approved within the current PRIA process. Currently no registered products have HAI claims and no formal process is in place for obtaining the claims on registered labels. A pathway does exist for potentially registering the type of product and active ingredient that you propose under the current registration framework but the PRIA timeframe may be problematic for your planning purposes, as Mike Ruley explained to me. As you may know, there are several current and proposed products that are used as a supplement to standard infection prevention practices. A statement to that effect would appear on the product label, as appropriate. In regard to your situation, the Agency is not currently considering to propose a new PRIA category since your product fits into the existing PRIA framework.

The new end product with a PRIA A540 category was started on 5/15/18 and is currently undergoing a technical screen. The PRIA date for this action is 10/15/18.

At the 4/27/18 meeting Mike mentioned that ABS was planning to submit the new active ingredient package to EPA within 30 days of the meeting. No submission has been received but a pre-submission meeting with AD has been scheduled for 6/11/18 to discuss the efficacy protocol. Your note below indicates that ABS will likely be submitting the registration submission package in 6-9 months. This action would be a PRIA A420 category with an 18-month decision time frame. Here is a link with more info on the A420 category: <https://www.epa.gov/pria-fees/a420-pria-fee-category>.

I hope this helps fill-in some of the holes for you. I've cc'd Steven Weiss from our Antimicrobials division on this note. He is likely the best expert for you to follow-up with should your group have further questions about the process.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

From: Stratton Edwards [mailto:sedwards@capitolhillcg.com]
Sent: Friday, June 1, 2018 2:43 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Mike Ruley <mruley@alliedbioscience.com>
Subject: Follow up to Allied BioScience meeting

Good Afternoon Nancy,

Thank you again for taking the time to meet with Mike Ruley, CEO of Allied BioScience and Jack Victory from our firm in April. Jack was stepping in for me that day as I had a family commitment. I am following up to that meeting to fill in holes since I was not there, and look for a some direction moving forward.

I understand there still is no clarity on where we land within the current categories that the EPA uses for different types of disinfectant claims for products that are used in hospital settings. Our coating is to be used **in conjunction with** disinfection products and practices, not replacing them. Am I correct then that the current category is not appropriate?

At the meeting, you had suggested that the best path forward would most likely be to create a new category for this unique technology versus changing the rule making process. I believe you stated that the next steps would be establishing sideboards, creating the category, and translating it into language for review. Would this be guidance, rulemaking, something else regulatory, or do you believe we need legislation?

ABS's first formulation, PRIA A540, is in review right now for Microbiostatic claims (mainly due to the limited nature of current established categories). The anticipated approval date is in October of this year. Their science team is scheduling a call with the EPA efficacy team (Kristen Willis) to review a new proposed protocol for residual activity of a polymer coating when used in conjunction with hospital disinfectants. We would anticipate using this approved residual protocol on both formulations and would submit for formal PRIA protocol review.

For the formulation with the new active ingredient (AI), we realize that even by creating a new category, ABS would not waive the requirements of registering a new AI. They are in the final stages of confirming the data requirements for the registration of this new AI and will perform testing concurrent to the protocol review. Based on the data requirements table that they are proposing, they anticipate completing the data sets and having a registration package submitted within 6-9 months.

You clearly know the impact our formulations could have in the interest of public health and we are eager to move as quickly as possible.

With that update on where we are with our submissions, what else—either on the new category development, or otherwise—do you need from us or should we be doing?

Thank you and I look forward to talking with you soon,

Stratton

Stratton Edwards
Legislative Counsel



Capitol Hill Consulting Group
Government Relations Professionals
499 S. Capitol Street, SW
Suite 608
Washington, DC 20003

Ex. 6

Office: (202) 488-0101
Web: capitolhillcg.com



