

From: Barry Cadden
Sent: Tuesday, April 24, 2012 2:59:00 PM
To: Mario Giamei, Jr.
Subject: RE: Fungal testing

YES....USP REGS STATE THAT THE LAB MUST INCUBATE FOR 14 DAYS.....THIS IS WHAT THEY DO

-----Original Message-----

From: Mario Giamei, Jr.
Sent: Tuesday, April 24, 2012 2:58 PM
To: Barry Cadden
Subject: FW: Fungal testing

Barry,

It seems like this lady is concerned because the state is paying them a visit coupled with the Franck's debacle. I had a long talk with her and I am pretty sure I need therapy now. That said, all of the testing data we have says 14 day incubation on the reports we send to the customers. Can I email this number to her? I think this solves her problem. After that its time to tell her nicely to pound sand. Of course I don't want to get down the road of testing for her customer product. Please advise.

Mario

-----Original Message-----

From: Nguyen, Ngoc [mailto:ngoc.nguyen@tenethealth.com]
Sent: Tuesday, April 24, 2012 1:45 PM
To: Mario Giamei, Jr.
Cc: Michael Thurston; Severin, Fe
Subject: RE: Fungal testing

Hi Mr. Giamei,

Thank you for your response regarding my sterility testing inquiry. Since fungi usually take longer to grow compared to bacteria, how long do you incubate the sample?

Thanks,
Ngoc

Ngoc Nguyen, Pharm.D., BCPS
Lead Clinical Pharmacist
San Ramon Regional Medical Center
6001 Norris Canyon Rd
San Ramon, CA 94583
Dir Tel: 925-275-6079
Fax: 925-275-8256

-----Original Message-----

From: Michael Thurston [mailto:mthurston@medicalsalesmgmt.com]
Sent: Monday, April 23, 2012 8:31 AM
To: Nguyen, Ngoc
Cc: Mario Giamei, Jr.
Subject: RE: Fungal testing

Ngoc,

Here is the answer I received from our QA team.

We do sterility testing which will pick-up any living microorganism but will not differentiate between specific fungal + bacterial organisms..but does not matter because if something is NOT sterile it is not usable. Your specific product is a special order drop so we will only have testing for "stock" solution that is used to build your drops..will not have testing for final product. The issue in Florida was an injectable oph dye, big difference in potential danger of contaminate injectable vs drop.

I hope that addresses your concerns. Please contact me or Mr. Giamei if you have further questions.

Regards,

Michael T. Thurston
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Mario G. Giamei Jr.
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-----Original Message-----

From: Nguyen, Ngoc [mailto:ngoc.nguyen@tenethealth.com]
Sent: Tuesday, April 17, 2012 4:33 PM
To: Michael Thurston
Subject: Fungal testing
Importance: High

Hi Michael,

Can you tell me if the QA team perform fungal testing on end products? The Los Angeles County Department of Public Health has identified 2 outbreaks of fungal endohthalmitis infections following intraocular use of products from a compounding pharmacy in Florida. Please let me know as soon as you can.

Also, did you get a chance to follow up on the out of range reports from Quarter 1 and 2 of 2010 (emailed you about this previously).

Thanks,
Ngoc

Ngoc Nguyen, Pharm.D., BCPS
Lead Clinical Pharmacist
San Ramon Regional Medical Center
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Fax: 925-275-8256

-----Original Message-----

From: General Board of Pharmacy Subscriber List [mailto:PHARM-GENERAL@LISTSERV.DCA.CA.GOV] On Behalf Of Board of Pharmacy
Sent: Monday, April 16, 2012 2:38 PM
To: PHARM-GENERAL@LISTSERV.DCA.CA.GOV
Subject: California State Board of Pharmacy Subscriber Alert

Please read the below health alert message released from the Los Angeles County Department of Public Health. The alert references products compounded in Florida and delivered to prescribers in California. Please contact the board if you have any questions or have received an