

**PRODUCT APPROVAL PROGRAM OVERSIGHT COMMITTEE
TELECONFERENCE MEETING FROM TALLAHASSEE, FLORIDA**

WEB URL : <https://global.gotomeeting.com/join/545051013>

AUDIO: DIAL-IN NUMBER 1 877 309 2070

CONFERENCE CODE/MEETING ID: 545-051-013

December 1, 2016

10:00 A.M. until completion

MINUTES

**PRODUCT APPROVAL PROGRAM OVERSIGHT COMMITTEE
PRESENT:**

Jeffrey Stone, Chairman
David Compton
David Gilson
Brian Swope

E.J. Carlson
Nan Dean
Robert Hamberger

STAFF PRESENT:

Mo Madani
April Hammonds
Chris Howell

Thomas Campbell
Zubeyde Binici
Jim Hammers

MEETING FACILITATION:

The meeting was facilitated by Jeff Blair from the FCRC Consensus Center at Florida State University. Information at: <http://consensus.fsu.edu/>

Welcome:

Time: 10:01 a.m.

Mr. Blair welcomed everyone to the teleconference call of the Product Approval Program Oversight Committee. He provided information for the callers on how to mute systems to avoid background noise.

Roll Call:

Mr. Blair performed roll call for the Product Approval Program Oversight Committee. A quorum was determined with 7 of 7 members present.

Agenda Approval:

Commissioner Compton entered a motion to approve the agenda as posted for today's meeting. Commissioner Hamberger seconded the motion. The motion passed unanimously with a vote of 7 to 0.

Approval of Meeting Minutes and Facilitation Report for October 3, 2016:

Commissioner Compton entered a motion to approve the minutes and facilitation report from October 3, 2016. The motion was seconded by Commissioner Hamberger. The motion passed unanimously with a vote of 7 to 0.

Product Approval and Entities Statistics Report:

Ms. Binici provided the statistical report for product approval and entities.

Conditional Approvals from October 2016 meeting:

All conditional approval requirements were met and completed.

BCIS enhancement update:

Mr. Madani provided an overview of the enhancement for the BCIS system.

Review of Product Approvals and Entity Applications:

Chairman Stone stated there were 7 entities on the consent agenda and asked for a motion for approval.

Commissioner Compton entered a motion to approve the consent agenda for the 7 entities. Commissioner Dean seconded the motion. The motion passed unanimously with a vote of 7 to 0.

Product Approval Applications without Comments consent agenda:

Chairman Stone advised there were 89 applications on the consent agenda. He stated that there was a mass e-mail sent out regarding a system glitch and asked that staff provide an explanation for the POC.

Mr. Madani provided an explanation of what occurred on the system and how this can be best rectified. He stated there were 12 applications that have been identified where the glitch caused issues with their applications. Mr. Madani stated that we are asking the POC to approve the 89 products without comments conditionally and Mr. Blair will provide the condition. He said additionally that we are asking the POC for permission to schedule an additional meeting between now and the February Plenary Meeting to allow for review of the revised applications to expedite the review by the POC and the Commission. Mr. Madani stated he would work with Chairman Stone to set the date.

Public Comment on Product Approval Applications without Comments consent agenda:

Mr. Anderson stated he would like to discuss his application.

Mr. Blair asked him to hold his discussion until the agenda had been completed.

Mr. Fine asked for further explanation of the conditional approval process and system glitch.

Mr. Madani explained the process as requested.

Ms. Hammonds stated that if Legal Counsel speaks with staff that the call needs to come through the Legal Staff representing the POC.

Product Approval Applications without Comments consent agenda (cont.):

Mr. Blair advised that the motion would be to conditionally approve the 89 applications on the consent agenda with the condition to allow staff the opportunity to work with the manufacturer to confirm that the uploaded files are updated and correct.

Chairman Stone asked for a motion to conditionally approve the consent agenda.

Commissioner Compton entered a motion to conditionally approve the 89 applications on the consent agenda with the condition to allow staff the opportunity to work with the manufacturer to confirm that the uploaded files are updated and correct. Commissioner Carlson seconded the motion. The motion passed unanimously with a vote of 7 to 0.

Product Approval Applications with Comments individual:

Mr. Blair stated the next motion should be for the 13 products on consent agenda for conditional approval the following 13 products based on the condition requested by the applicant to rectify system retention of uploaded documents as identified by staff. The 13 products are **7640R7, 8871R7, 10975R6, 12161R1, 15166R1, 12169R1, 12184R1, 12186R1, 15211R4, 15099R6, 16853R4, 16854R4 AND 2123.**

Chairman Stone asked for a motion on the 13 applications for conditional approval.

Commissioner Compton entered a motion to conditionally approve the 13 products on the condition requested by the applicant to rectify system retention of uploaded documents as identified by staff. Commissioner Carlson seconded the motion. The motion passed unanimously with a vote of 7 to 0.

Mr. Blair advised that there were 6 additional applications that will need to be taken individually as they have specific conditions associated with them. He stated he will provide the specific conditions.

FL13749 R5:

Commissioner Compton entered a motion for conditional approval. Commissioner Carlson seconded the motion. The motion passed unanimously with a vote of 7 to 0.

FL17490:

Commissioner Compton entered a motion for conditional approval. Commissioner Compton seconded the motion. The motion passed unanimously with a vote of 7 to 0.

Product Approval Applications with Comments individual (cont.):

FL20766 R1:

Commissioner Compton entered a motion for conditional approval. Commissioner Carlson seconded the motion. The motion passed unanimously with a vote of 7 to 0.

FL 21195:

Commissioner Compton entered a motion for conditional approval. Commissioner Carlson seconded the motion. The motion passed unanimously with a vote of 7 to 0.

FL 21353:

Commissioner Compton entered a motion for conditional approval. Commissioner Carlson seconded the motion. The motion passed unanimously with a vote of 7 to 0.

FL 21382:

Commissioner Compton entered a motion for conditional approval. Commissioner Carlson seconded the motion. The motion passed unanimously with a vote of 7 to 0.

Public Comment:

Mr. Anderson discussed the issues he had with **FL 21388** in detail. Mr. Anderson requested that this product be voted on also today under conditional approval with the other 89 applications.

Mr. Madani explained what had occurred within the system from the staff standpoint. He stated that this was not possible as the POC nor the public had the opportunity to review and make comments.

Mr. Hammonds stated that due to the fact that this product had not been published for POC review or the public the POC could not vote on it today based on the lack of information available for review.

Mr. Madani stated that it could be added to the expedited agenda thus allowing time for review by all.

Mr. Anderson stated that would be acceptable.

Commissioner Compton entered a motion to add **FL 21388** to the expedited agenda for review. Commissioner Carlson seconded the motion. The motion passed unanimously with a vote of 7 to 0.

DBPR Applications:

Mr. Madani stated there were 2 with comments and the staff is working with them and there is no action needed for these applications.

Public Comments:

Mr. Gascon made comments on the approval methods on the BCIS QA section C 3 on the agenda.

Mr. Anderson added additional comments on the QA through BCIS.

Mr. Madani responded to the comments and questions.

POC Comments:

There were no POC comments.

Second Roll Call:

Mr. Blair performed a second roll call; all seven original members were still on the line.

Adjournment:

Chairman Stone adjourned the meeting at 10:39 am.