

From: Raji Tripathi
To: Les Cupidon
Date: 05/22/2007 9:14:23 AM
Subject: Fwd: ADDENDUM — CRGR BRFG. ON GIP CHANGES/MD 6.4 UPDATE

Les,

Pl. include this in your mtg. mts., as a background.

Thanks...Raji
Via CITRIX; 0915

>>> Raji Tripathi Tuesday, May 22, 2007 >>>
Hi Gary,

In reference to the CRGR brfg. yesterday on the ongoing improvements to the GI Program including revision to the program guidance, there is one minor point that I would like to clarify:

When discussing the GI process flow chart, you had mentioned that the CRGR gets involved only when the staff develops the regulatory solution and brings to the Committee for endorsement. That is absolutely correct. However, I should have made a note at that point that although the active participation of the CRGR is only at the "tail end," under the existing guidance, the Committee would receive a for-information copy of the staff's risk/security assessment as well as the technical/regulatory assessment, when they are completed. By a copy of the Memorandum sent to the EDO, the CRGR would also be notified of the endorsement, if any, by either the ACRS or ACNW.

This change (to expand and clarify the roles of the advisory committees) was made in 2005 at the last revision of MD 6.4, when we updated the program guidance as a result of one of the several recommendations by the Davis Basse Lessons Learned Task Force: to simplify the process for submitting the GIs and also clarify the roles and responsibilities of the advisory Committees, including the CRGR.

Under the new GIP, in our proposed graded approach, we may not for every GI go to the advisory committees for endorsement of each decision. In some cases, the panel recommendation and the joint decision by the Director, RES, and the regulatory office would suffice. However, in the event a GI is closed without a regulatory action (new or revised generic communications, regulation or regulatory guidance), all the advisory committees will be informed of the outcome, by a copy of the closure memorandum sent to the EDO.

Let me know if you or other members have any questions.

Raji
Via CITRIX; 0753 hrs

CC: Raji Tripathi

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Subject: ADDENDUM — CRGR BRFG. ON GIP CHANGES/MD 6.4
UPDATE

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05/22/2007 7:53:48 AM

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Expiration Date: None
Priority: High
ReplyRequested: No
Return Notification: None

Concealed Subject: No
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Junk Mail settings when this message was delivered

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