

## Boocker, Nancy

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**From:** Sadove, Elizabeth  
**Sent:** Sunday, October 30, 2005 10:20 PM  
**To:** Axelrad, Jane A  
**Cc:** Boocker, Nancy  
**Subject:** RE: Cbe and plr

Rachel called me this evening... she would like language sent to Sheldon in the a.m. I will come into the office instead of going to the GAO meeting tomorrow morning. This way, I can get a better idea as to whether I need to send language ASAP or not. Martha is going to the GAO meeting and can cover. Thanks, Liz

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

From: Axelrad, Jane A  
Sent: Saturday, October 29, 2005 9:07 AM  
To: Sadove, Elizabeth  
Subject: Fw: Cbe and plr

Fyi. Steven will talk to Sheldon.

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Sent from my BlackBerry Wireless Handheld (www.BlackBerry.net)

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

From: Axelrad, Jane A <AXELRADJ@cder.fda.gov>  
To: Galson, Steven <GalsonS@cder.fda.gov>; Behrman, Rachel E <BEHRMAN@cder.fda.gov>; Jenkins, John K <JENKINSJ@cder.fda.gov>  
Sent: Sat Oct 29 08:19:17 2005  
Subject: Re: Cbe and plr

Steven: I think you should discuss with Sheldon whether to change the existing 314.70 to match what we're doing with the highlights so the rule makes sense. Maybe we should take out the provision of 314.70 that allows changing a warning or precaution with a CBE. Were going to have a lot of questions about this if it goes out with this ambiguity.

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Sent from my BlackBerry Wireless Handheld (www.BlackBerry.net)

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

From: Galson, Steven <GalsonS@cder.fda.gov>  
To: Behrman, Rachel E <BEHRMAN@cder.fda.gov>; Axelrad, Jane A <AXELRADJ@cder.fda.gov>; Jenkins, John K <JENKINSJ@cder.fda.gov>  
Sent: Fri Oct 28 19:47:39 2005  
Subject: RE: Cbe and plr

Rachel  
thanks for trying

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

From: Behrman, Rachel E  
Sent: Friday, October 28, 2005 6:42 PM  
To: Axelrad, Jane A; Jenkins, John K  
Cc: Galson, Steven  
Subject: Cbe and plr

We discussed the cbe issue with Sheldon who stated unequivocally that without the cbe language the rule will not go forward (this is per the White House).

## Sherman, Aaron

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**From:** Norden, Janet M  
**Sent:** Wednesday, July 16, 2008 1:14 PM  
**To:** Sherman, Aaron  
**Subject:** Print

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

From: Jenkins, John K  
Sent: Thursday, August 09, 2007 2:27 PM  
To: Burke, Laurie B; Colangelo, Kim M  
Cc: Kweder, Sandra L; Norden, Janet M  
Subject: RE: Internal discussion on NDA 22-059, Tykerb (lapatinib)

A little more detail now that I am not thumb typing.

OCC has a high priority proposed rule in which they plan to add a couple of phrases to clarify what they view as our long standing intent for the CBE regulations for labeling changes. This is related to various litigations that are proceeding and may go to the Supreme Court. So, the goal for the publication of the PR is late August with a final before the end of the year. Jane is looking to see if we can get anything added to help with the PLR issue, but we are not optimistic since the impetus for the PLR PAS came from the department and Sheldon did not seem inclined to argue for a change. That is why there is also a parallel track (and a lot of e-mail today) in trying to find a waiver provision that we can apply and "sell" to OCC.

John

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

From: Burke, Laurie B  
Sent: Thursday, August 09, 2007 11:51 AM  
To: Colangelo, Kim M; Jenkins, John K  
Cc: Kweder, Sandra L; Norden, Janet M  
Subject: RE: Internal discussion on NDA 22-059, Tykerb (lapatinib)

In a meeting with OPS and Paula McKeever from Jane's group about the 314.70 reg rewrite yesterday, we learned that OCC/Bradshaw is working on a change in those regs that will redefine CBE submissions and trump our initiative for the time being. They are working with Rachel B on this. I'm hoping that was one of the options you discussed yesterday, John.

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

From: Colangelo, Kim M  
Sent: Thursday, August 09, 2007 9:28 AM  
To: Jenkins, John K  
Cc: Burke, Laurie B; Kweder, Sandra L; Norden, Janet M  
Subject: RE: Internal discussion on NDA 22-059, Tykerb (lapatinib)

John,

We had scheduled an internal meeting (you, Sandy, Laurie, Janet Norden and myself) to discuss this matter as well (August 21 at 2:00). Is there still value in holding this meeting, or are we in a holding pattern again?

Kim

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

From: Jenkins, John K  
Sent: Wednesday, August 08, 2007 9:06 PM  
To: Jones, Glen D (CDER); Axelrad, Jane A; CDER SEALD Labeling; Burke, Laurie B; Bernstein, Michael; Rosario, Lilliam; Pierce, William (CDER); Colangelo, Kim M; Sadove, Elizabeth; Kweder, Sandra L; Ray, Seth; Loewke, Sally A; Norden, Janet M