From: Lee, Bonnie
Sent: Tuesday, November 29, 2005 10:00 AM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: Parallel track drugs
Dear [Redacted], Your email to CDER was referred back to us for response. The advice I provided below would apply; although the "at" in the second line should be an "as". When you asked about parallel track studies and indicated you were writing IRB guidelines to deal with them, I will admit that I wondered what you would say about those studies that would differ from your standard operating procedures. Again, I'm sorry I can't be more helpful. If you're at the same institution as [Redacted]...please give her my regards.

My best,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
-----Original Message-----
From: Lee, Bonnie On Behalf Of OC GCP Questions
Sent: Monday, November 28, 2005 12:15 PM
To: [Redacted]
Subject: RE: Parallel track drugs
[Redacted], My understanding is that the IRB's review responsibilities are the same for parallel track studies at for other types of studies. The only exception would be if FDA waived some requirement related to IRB review, but that would be protocol specific. Sorry that I can't be more helpful.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
-----Original Message-----
From: [Redacted]
Sent: Monday, November 28, 2005 10:43 AM
To: OC GCP Questions
Subject: RE: Parallel track drugs
Thank you Bonnie,

I have reviewed several of the documents you refer to but could not get an idea of what our local IRBs role is, if any, in reviewing such protocols.
I will try CDER to see if they have any additional input.

Thank you so much for your help. Hope your holiday was nice.

[Redacted]
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immediately notify the sender by reply E-mail, or call[Redacted] and delete this message and its attachment(s).

From: Lee, Bonnie [mailto:BLee@OC.FDA.GOV] On Behalf Of OC GCP Questions
Sent: Friday, November 25, 2005 1:42 PM
To: [Redacted]
Subject: RE: Parallel track drugs
[Redacted], The parallel track mechanism is used so infrequently (only one drug has been approved under that mechanism), that I really can't give you a meaningful answer. You might want to go to FDA's website at www.fda.gov and enter "parallel track drugs" in the search area; a lot of good documents come up. In particular, the one
at: http://www.fda.gov/oashi/aids/expanded.html describes the various expanded access mechanisms available including those pertaining to parallel track. The relevant sections that appear to respond to your question in part state:

"... Expanded Access Mechanisms
Expanded access mechanisms are designed to make promising products available as early in the drug evaluation process as possible to patients without therapeutic options, either because they have exhausted or are intolerant of approved therapies.
Expanded access mechanisms include Treatment IND protocols and parallel track protocols. In addition, the ordinary development of drugs under an IND includes a variety of open studies that also provide access to drugs. FDA monitors each of these access programs on an ongoing basis....
...Parallel Track (1992)
The final PHS policy statement on the parallel track mechanism was published in the Federal Register on April 15, 1992. The purpose of the parallel track policy was to expand the availability of promising investigational drugs to those persons with AIDS and HIV-related diseases who are without satisfactory alternative therapy and who cannot participate in controlled clinical trials. The policy differs from the treatment IND primarily in that it applies only to AIDS and HIV-related diseases, and that investigational drugs could be made available earlier in the development process.
Stavudine (d4T) is the only drug that was submitted for consideration under the parallel track policy. The protocol was allowed to proceed on October 5, 1992. Approximately 12,000 patients received Stavudine through the parallel track mechanism. An accelerated new drug application for stavudine was approved June 17, 1994. The application received full marketing approval on December 21, 1995...."
I'm sorry that I can't be more helpful to you. I hope your Thanksgiving was a pleasant one for you.
Sincerely,
Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.
-----Original Message-----
From: [Redacted]
Sent: Wednesday, November 23, 2005 8:29 AM

To: gcpquestions@oc.fda.gov
Subject: Parallel track drugs
FDA,
[Redacted] is in the process of revising our SOP s on how our office and the IRB operates in general. We have now reached a point where we have a draft SOP on parallel track drugs. Could you tell me a little about how the process of reivew and approval of these drugs work at the FDA?
Your help with this is much appreciated.
Sincerely,
[Redacted]
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