From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, September 09, 2004 12:09 PM
To: [Redacted]
Subject: RE: Guidance for cancer drugs

Dear [Redacted],

Try: www.fda.gov/cber/gdlns/indcancer.pdf

The guidance was finalized in January 2004. In it's introduction, some history of the guidance is given, as you suggested. I hope this is helpful to you.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy, GCPP, FDA

> -----Original Message-----
> **From:** [Redacted]
> **Sent:** Wednesday, September 08, 2004 3:09 PM
> **To:** gcpquestions@oc.fda.gov
> **Subject:** Guidance for cancer drugs
>
> I cannot find the guidance entitled "IND Exemptions for Studies of Lawfully Marketed
>
> Cancer Drug or Biologic Products" which was posted at:
> http://www.fda.gov/cder/guidance/3760dft.pdf
>
> Has it been withdrawn?
>
> It would be helpful if FDA would post a history of guidances, as OHRP does.
>
> Any insight you can provide into the fate of this guidance document would be appreciated.
>
> [Redacted]