Health Canada Santé Canada

Therapeutic Products Directorate
5th Floor, Holland Cross, Tower B
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OTTAWA, Ontario
K1A 0K9

Your file Votre référence

Our file Notre référence

22 November 2010

9427-A1635-57C

Erica Thorson, MPH
Regulatory Compliance Associate II
Radiation Therapy Oncology Group
American College of Radiology
1818 Market Street, Suite 1600
PHILADELPHIA, Pennsylvania
USA 19103
(215) 940-8824

No Objection Letter RE: Amendment # 3 to Protocol # RTOG 0724

Dear Ms. Thorson:

This is to advise you that the data concerning your Clinical Trial Application for **CARBOPLATIN/ CISPLATIN/ PACLITAXEL**, control number **142779** which were received on November 8, 2010, have been reviewed and we have no objection to the amendment to the study. Please note that a new control number has been assigned to this Clinical Trial Application Amendment only. Any correspondence relating to the original CTA should be referenced to the original control number assigned.

I would remind you of the necessity of complying with the *Food and Drug Regulations,* Division 5, in the sale of this product for clinical testing. You are also reminded that all clinical trials should be conducted in compliance with the Therapeutic Products Directorate's *Guideline for Good Clinical Practice.*

Please note that for drugs marketed in Canada and in clinical trials, any serious and unexpected adverse drug reaction occurring inside or outside Canada should be reported to both MHPD and TPD until completion of the trial then the reports should be sent to MHPD only.

Should you have any questions concerning this letter, please contact the Office of Clinical Trials at (613) 941-2132.

Yours sincerely,

C. Lourenco, Ph.D.
Manager - Clinical Trials Group I
Office of Clinical Trials

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