${vault:document\_application\_\_vr.fda\_reviewer\_\_v}
${vault:document\_center\_ectd\_\_vr.address\_line\_1\_\_v}

${vault:document\_center\_ectd\_\_vr.address\_line\_2\_\_v}

${vault:document\_center\_ectd\_\_vr.address\_line\_3\_\_v}

${vault:document\_center\_ectd\_\_vr.city\_\_v}, ${vault:document\_center\_ectd\_\_vr.state\_center\_\_v}, ${vault:document\_center\_ectd\_\_vr.zip\_code\_\_v}

**Subject:** ${vault:document\_promotional\_material\_document\_type\_\_vr.name\_\_v} for ${vault:document\_application\_\_vr.application\_type\_\_v} ${vault:document\_application\_\_vr.application\_number\_\_v} ${vault:document\_product\_\_vr.name\_\_v} ${vault:document\_product\_\_vr.generic\_name\_\_c} ${vault:document\_dosage\_\_vr.name\_\_v}

Dear ${vault:document\_application\_\_vr.fda\_reviewer\_\_v},

Pursuant to section ${vault:document\_center\_ectd\_\_vr.section\_\_v} enclosed please find the presubmission of ${vault:professional\_consumer\_\_v} ${vault:document\_promotional\_material\_document\_type\_\_vr.name\_\_v}, ${vault:launch\_material\_type\_\_v} promotional materials for ${vault:document\_application\_\_vr.application\_type\_\_v} ${vault:document\_application\_\_vr.application\_number\_\_v} ${vault:product\_\_v} ${vault:document\_product\_\_vr.generic\_name\_\_c} ${vault:document\_indication\_\_vr.indication\_\_v}.

|  |  |  |  |
| --- | --- | --- | --- |
| Material Type | Material ID | Material Description | Product |
| ${vault:document\_promotional\_material\_information\_\_vr.documents\_\_vr.material\_type\_\_v} | ${vault:document\_promotional\_material\_information\_\_vr.documents\_\_vr.promotional\_document\_number\_\_v} | ${vault:document\_promotional\_material\_information\_\_vr.documents\_\_vr.name\_\_v} | ${vault:document\_promotional\_material\_information\_\_vr.documents\_\_vr.product\_\_v} |

This submission includes the following for each promotional material identified above:

* Clean Version(s) of each draft promotional material(s)
* Annotated Version(s) of each draft promotional material(s)
* The current FDA Approved PI and/or Medication Guide for ${vault:product\_\_v}
* Annotated reference(s) to support product claim(s) for each promotional material(s)

Should you have questions or require additional information regarding this submission please contact ${vault:document\_pm\_contact\_\_vr.name\_\_v} at ${vault:document\_pm\_contact\_\_vr.telephone\_\_v} or via email at ${vault:document\_pm\_contact\_\_vr.email\_\_v}.

Regards,

${vault:document\_pm\_contact\_\_vr.name\_\_v}

This submission is virus free as checked by virus checking software name version number created by virus checking software company.