

2. Summary of proposed changes

For multiple variations (grouped variations), reproduce this section and provide separate summaries for each proposed variation.

2.1 Variation(s) to:

- Administrative Information
- Manufacturing
- Quality Control
- Safety
- Efficacy
- Annual variation for human influenza vaccines
- Other (s)
For other (s) please provide details below

.....
.....

2.1 Variation title and number:

2.2 Summary of current and proposed details:

Current details	Proposed details

2.3 Reason for change:

2.4 Date of implementation:

3. Documentation checklist

The following documents have been submitted together with this application form:

<i>Note: All documents must be provided for this application to be valid.</i>	
Supporting documentation <i>All supporting documents as stipulated for the change in the Guidance on Variations to a Biological Product are included in this submission</i>	Yes <input type="checkbox"/>

4. Declaration

Please check all declarations that apply.

I declare that:

- For each change all conditions as stipulated in the *Guidance on Variations to a Biological Product* for the change requested are fulfilled.
- There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.
- Where applicable, national fees have been paid
- The information submitted is true and correct.

Name:

Signature: Date: ____/____/____