16 February 2012
EMA/CHMP/539928/2010

Application form

For a post-consultation procedure on an ancillary medicinal substance in a medical device

European Medicines Agency (EMA) procedure number[1]: EMEA/H/D/<Number>

Type of application (tick all applicable options)

☐ Minor amendment (equivalent to Type IA)

☐ Minor amendment (equivalent to Type IB)

☐ Major amendment (equivalent to Type II)

Changes concern (for Type IB and Type II variations only, tick all changes applicable)

☐ Quality

☐ Non-clinical

☐ Clinical

☐ Other

Name and address of the applicant (notified body):	Name and address of contact person[2]:
<Name> <Address> <Postcode> <City> <Country>	<Name> <Address> <Postcode> <City> <Country> Telephone number: <Number> Fax number (optimal): <Number> E-mail: <E-mail address>

[1] The sequential EMA procedure number (not the applicant's internal number) should be provided here, when known to the applicant.
[2] If different from the authorised contact point, please provide a letter of authorisation.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8545
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Medical device(s) concerned by this application[3]

EMA number	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
<EMA product number {EMEA/H/D/0000/00/00/00}>	<Name>						

Or,

EMA number	(Invented) Name	Strength
<EMA product number {EMEA/H/D/0000/00/00/00}>	<Name>	

[3] If this list is very extensive (more than one page) it may be added as annex to the application form. The format to be used should be the same as Annex I of the initial consultation procedure.

Changes included in this application

The changes included in this application are classified as:

Changes in an ancillary medicinal substance incorporated in a medical device (post-consultation procedure)			Procedure type
☐	a)	Minor change (equivalent to type IA)	IA
☐	b)	Minor change (equivalent to type IB)	IB
☐	c)	Major change (equivalent to type II)	II

The post-consultation procedures on an ancillary medicinal substance in a medical device are classified as minor/major amendments by analogy to Commission Regulation (EC) 1234/2008 and the Commission Classification Guideline for variations on marketing authorisation for medicinal products.

By analogy, the proposed changes could be classified as:

Variation number*	Procedure type
	☐ IA ☐ IB ☐ II

* According to the classification guideline.

Precise scope and background of the changes[4]:

<Text>

Present[5]	Proposed[5]
<Text>	<Text>

Other applications under revision (if applicable):

<Text>

Documentation provided[6]:

<Text>

[4] Include a description and background of all proposed changes.
[5] Specify the precise present and proposed wording or specification, including dossier section number(s) at the lowest possible level.
[6] Include a description of all the documentation provided.

Declaration of the applicant

I hereby submit a notification/application for the above consultation procedure(s) to be varied in accordance with the proposals given above. I declare that (*please tick the appropriate declarations*):

☐ There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel).

☐ The changes do not adversely affect the usefulness of the ancillary medicinal substance as part of the medical device as initially verified by the notified body.

☐ Where applicable, all conditions as set for the variation(s) concerned are fulfilled.

☐ For type IA notifications: the required documents as specified for the changes concerned in analogy to Commission Classification Guideline for variations on marketing authorisation for medicinal products have been submitted.

☐ Where applicable, fees have been paid.

Changes will be implemented from[7]: ☐ Next production run/next printing.

☐ Date: <DD Month YYYY>.

Main signatory[8]: _____ Print name: <Name>	Status (job title): <Job title> Date: <DD Month YYYY>
Second signatory: _____ Print name: <Name>	Status (job title): <Job title> Date: <DD Month YYYY>

[7] Only to be completed for type IB and type II variations.
[8] The signature of the main signatory is mandatory.