



e-form

Notification of Changes to Labelling and Package Leaflets in accordance with article 61(3)



Office use only:
Application received on:

APPLICATION FORM

PLEASE USE THE GUIDELINES FOR FURTHER INFORMATION.

1 PRODUCT DETAILS

1.1 (a) Product Name:

1.1 (b) Active
substance/s:

1.1 (c) Pharmaceutical
Form:

1.1 (d) Strength/s:

1.1 (e) Marketing
Authorisation Number/s:

2 Authorisation Holder / Contact Person/s

2.1 Marketing Authorisation Holder

Name:

Address:

Telephone:

E-mail:

2.2 Person / Company Authorised for Communication / Signing of documents on behalf of the Authorisation Holder

Name:

Address:

Telephone:

Fax:

E-mail:

3 Declaration

This notification is submitted under Article 61(3) of Council Directive 2001/83/EC. I hereby confirm that the conditions associated with the change have been met and that no other changes have been introduced.

3.1 I declare that (Please tick if applicable):

The amended actual size colour mock-ups have been submitted.

There are no other changes than those specified in this application.

The amended package leaflet has been submitted.

The change/s do not affect the Summary of Product Characteristics.

The change/s will not have an impact on the quality, efficacy and safe use of the product.

The required supporting information has been submitted.

3.2 Date when proposed change will be implemented

3.3 Name of the Applicant (Block Letters):

Signature/s:

Position:

Place and Date:

4 Details of change/s:

Changes notified fall into the following categories:

(Give a brief explanation for the proposed changes to labelling and /or package leaflet.

Provide one full mock-up of the currently approved labelling and package leaflet, one full mock up of the proposed labelling and package leaflet (hard and electronic copies) clearly indicating the proposed changes)