Please note that in order to add a catalogue number the device must already exist on a licence. The purpose of the attached fax-back form is to extend the same product line.

1. The purpose of the attached form is to facilitate the approval of device licence amendments where the change involved consists of the addition or deletion of new catalogue or model numbers that represent *non-significant changes* (Section 34) and that are within the guideline of the various application types (Sections 28 to 31) of the Medical Devices Regulations. To determine whether your amendment represents a *non-significant change* and for more information on the various application types please refer to the following guidance documents:

<table>
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<tr>
<th>Guidance Document</th>
<th>Website URL Address</th>
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2. The attached form **must** be submitted with a copy of page 1 of the applicable licence to be amended.

3. **All sections below must be completed for this fax-back form to be processed.** Incomplete forms will result in the licence amendment fax-back form being rejected.

4. Receipt of a MDB-signed fax-back form is considered to be authorization that your licence is amended and therefore, the device and specified catalogue numbers can be sold. Your amended licence will follow by mail.

5. It is the intention of the MDB to process Licence Amendment Fax-Back forms within 7 calendar days from the date of receipt.

6. **Do not use both the Amendment Fax-Back Form and a regular Amendment Application for the same amendment.**

7. Please note that this form is not to be used for Private Label licences.

8. Please identify the device(s) being added (include the trade name).

(June 2008)
Therapeutic Products Directorate use

Licence Number to be Amended __________________________ Application Number __________________________

LICENCE AMENDMENT FAX-BACK FORM
FOR NON-SIGNIFICANT ADDITIONS/DELETIONS OF CATALOGUE NUMBERS ONLY

FAX TO THE THERAPEUTIC PRODUCTS DIRECTORATE AT (613) 957-6345
* NOTE: PLEASE PROVIDE ONE FAX-BACK FORM PER LICENCE TO BE AMENDED

1) RATIONALE (Please specify the nature of the proposed change. In addition, please confirm that the proposed change does not alter the original range of sizes licensed, or original indications for use, etc.)

2) CATALOGUE NUMBERS (Which catalogue numbers are being added/deleted? If a catalogue number is added and the associated device contains ≥ 0.1% w/w of DEHP or is manufactured from raw materials containing or derived from BPA, please check the appropriate box. Please consult the document “Guidance for Industry: How to Complete the Application for a New Medical Device Licence”, which is available on the website, for the definition of DEHP and BPA.)

<table>
<thead>
<tr>
<th>Device ID No.</th>
<th>Model or Catalogue No.</th>
<th>Add = A</th>
<th>Change = C</th>
<th>Delete = D</th>
<th>Device contains ≥ 0.1% w/w of DEHP (check if applicable)</th>
<th>Device is manufactured from materials containing or derived from BPA (check if applicable)</th>
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</table>

Please use additional pages if necessary using this same format (Note catalogues, computer printouts, etc. will not be accepted).

3) CERTIFICATION
This certifies that, in accordance with the Medical Devices Regulations issued July 1998, the amendment(s) described above does not constitute a significant change.

Name of Manufacturer Senior Official/Signature __________________________ Date __________________________

4) E-MAIL ADDRESS TO WHICH MDB SHOULD SEND THE LICENCE, **ONLY IF DIFFERENT THAN THE E-MAIL ADDRESS OF THE REGULATORY CONTACT ON FILE WITH MDB:

FOR MEDICAL DEVICES BUREAU (TPD) USE ONLY:

Date Fax-Back Complete __________________________ Signature __________________________

(June 2008)