Health Canada / Santé Canada

Good Manufacturing Practices –
Request for Assessment of a Foreign Building Form (FRM-0213)

SECTION 1: REQUESTER INFORMATION	
Company Name:	
Drug Establishment Licence number : (* Include letter at end of DEL#)	
Contact Person:	Title:
Telephone No.:	Fax No:
E-mail address:	

SECTION 2: FOREIGN BUILDING INFORMATION		
Foreign Building Name:		
Street:	Suite No.:	Post Office Box:
City:	Province/State:	
Country:	Postal/Zip Code:	

SECTION 3: DRUG INFORMATION

Product Name and/or DIN	Activity	Category	Class of Dosage Form		Sterile (Y/N)
	F = Fabricate P = Package/ Label T = Test a. Biological b. Chemistry c. In-process d. Microbiological – Sterility e. Microbiological f. Physicochemical g. Stability h. Other (specify)	1 = Pharmaceutical 2= Active Pharmaceutical Ingredient 3 = Vaccine 4 = Blood & Blood Components 5 = Biological 6 = Radiopharmaceutical	**Finished Dosage Form (FDF)** 1 = Powder for solution 2 = Tablet 3 = Capsule 4 = Solution 5 = Suspension 6 = Aerosol 7 = Powder 8 = Suppository 9 = Medical Gas 10 = Veterinary Premix 11 = Bulk Intermediates (biological only) 12= Other (Specify)	**Active Pharmaceutical Ingredient (API)** 13= Solid 14= Liquid 15= Gas	

If you indicated non-sterile API, is the API being used to manufacture a sterile or non-sterile Drug in Dosage Form? ☐ Yes ☐ No

SECTION 4: STATUS OF FOREIGN BUILDING

1. Is the building listed on your DEL or Table A? ☐ Yes ☐ No
2. Are you adding the building in support of a Drug Submission? ☐ Yes ☐ No
   a. If yes, when are you planning to submit the drug application?
3. Have you contacted the foreign building to notify them of the request you

have submitted for an on-site assessment by Health Canada? ☐ Yes ☐ No

a. If yes, have they proposed dates? ☐ Yes ☐ No

b. If yes again, what are the proposed dates?

4. Has the building fabricated, packaged/labelled or tested drugs destined for the Canadian market in the past 4 years? ☐ Yes ☐ No

a. If yes, since when?

b. If no, when do they expect to start activities for drugs destined for the Canadian market?

5. To the best of your knowledge, is there a planned inspection by a [1]Qualified/ [2]Regulatory Authority at this time? ☐ Yes ☐ No

a. If yes, by whom and when?

6. To the best of your knowledge, has there been a recent inspection by a [1]Qualified/[2]Regulatory Authority? ☐ Yes ☐ No

a. If yes, by whom and when?

[1]**Qualified authority**-An authority listed as a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S)

[2]**Regulatory authority**- A government agency or other entity in an MRA country that has a legal right to control the use or sale of drugs within that country and that may take enforcement action to ensure that drugs marketed within its jurisdiction comply with legal requirements.

SECTION 5: RATIONALE FOR REQUEST

SECTION 6: AVAILABLE DOCUMENTATION

Is a Site Master/Reference file available? ☐ Yes ☐ No

* Do not submit the SMF/SRF with this request. It is to be provided upon request

SECTION 7: AUTHORIZATION

Name of Authorized signing official:	**Title:**
Signature:	**Date:**