

Table A: Instructions

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1 About Table A

Table A is an annex to [FRM-0033](#), the form prescribed by the Minister to submit an application for a Drug Establishment Licence (DEL). In addition to submitting a [FRM-0033](#), you must also submit a Table A when submitting an application to:

- amend the Active Pharmaceutical Ingredient (API) Foreign Building annex to your DEL or;
- add an API Foreign Building Annex to your DEL or;
- add an API Foreign Building Annex as part of a New DEL application.

For more information on the DEL requirements for API and List A API (for veterinary use) you can consult the [Guidance on Drug Establishment Licences and Associated Fees \(GUI-0002\)](#). The following sections of GUI-0002 would be the most relevant:

- Section 7: Category of Drugs, provides further clarifications with respect to drug categories including API and List A API.
- Section 15. The DEL and its Annexes, outlines the information listed on the different sections and annex of the DEL, including the DEL API Foreign Building Annex.

For information on the good manufacturing practice (GMP) requirements applicable to API foreign building applications consult, [How to demonstrate foreign building compliance with drug good manufacturing practices \(GUI-0080\)](#).

2 Mechanics of the form

Table A is an Excel based form that uses macros, so it is important to ensure that content is "Enabled" before proceeding. To do this click the "Enable Content" button that appears as part of the "Security Warning" under the excel toolbar when you launch the form. If the content is not enabled the functionality of the Table A will not work, specifically the row 4 including the picklists, built in logic regarding the required fields (outlined further in [Table A columns](#)) and the buttons.

If you have any issues with enabling the macros of the form, please contact us at hc.del.questions-leppp.sc@canada.ca.

2.1 Row 4

When entering information into Table A, use Row 4. Using Row 4 will help you fill the form without deficiencies. When using Row 4, use the picklist to enter information whenever possible rather than using free text. This will help you complete the table accurately, consistently, and reduce the chance of deficiency. More information on each picklists is available in the [Table A Columns](#) section below. Once a row is complete, click the orange button in row 3 to add the data from row 4 into the form.

Other buttons, located after Column V are available to assist you in using Row 4 effectively.

2.2 The buttons

The buttons at the end of the table (to right of Column V) are there to assist you in using Row 4 effectively.



In the description outlined below of the button functionality, “selected row” means to either a) select a cell in the row or b) selecting the whole row.

Copy Selected Row, to Row 4:

Copies the contents of the selected row’s data to Row 4. This allows you to use the contents of the original row so that you do not need to re-enter information. For example if you have multiple APIs with the same information in every other column, this button would allow you to copy the contents and just update the API name.

Delete Select Row

Removes the selected row and its contents. If the data is not deleted using this button, a blank row will remain.

Clear Table

Clears the data from all rows with the exception of Row 4.

Clear Row 4

Clears the data in Row 4 only.

3 Table A columns

Column A – Change Request

This column will be how you communicate the change you are making to Table A. The type of change you select from the picklist will determine which cells in row 4 are required for your change request. These requirements are outlined in [Section 4](#).



When a “Change Request” is selected in row 4 each subsequent cells of row 4 will be identified as one of the three following requirement types:

- 1) If the cell is required it will display as blank and you must enter/select data in order to add the data to the table.
- 2) If the cell is optional it will display as “optional” and you will be able to enter/select data.
- 3) If a cell is not required then in Row 4 the cell will display as “N/A” and you will not be able to enter anything in that cell.

Column B & C – DEL# and building letter

These two columns are required for all Table A applications with the exception of New DEL applications (i.e. application submitted by a person that does not hold a DEL) as this information is not available to you. Only one domestic building should be listed per Table A. If applying for more than one domestic building submit multiple Table A forms.

Column D – Imported As

This identifies whether you are importing the molecule as an API or as a finished dosage form. “A” means you are importing the API listed in column E and “F” means that the API listed in column E is transformed into an FDF outside of Canada and you are importing an FDF containing the API in column E. This column has coding linked to it, so if you indicate imported as “A” for API, then Column S & T (FDF foreign building information) are not required. If you indicate imported as “F” for finished dosage form, then Column S & T are required.

Column E - API Name

The picklist is populated using API names from Health Canada’s [Drug Product Database](#) (DPD). For all API used in the fabrication of a DIN drug, you must use the API name from the picklist that match the API nomenclature approved by Health Canada and available in the DPD.

In cases of an API that is not used to manufacture a DIN drug, such as API imported for compounding only the API may not be listed in the DPD and in this cases would not be available in the picklist. Only in these rare cases is it acceptable to enter the API name using the free text option. When using free text, the reason for using free text has to be selected from the picklist in Column F. Using free text inappropriately will cause a deficiency.

Note: you are only to enter one API name per line of Table A.

Column F - Reason for using API free text in column E

When using free text in column E you must select the reason why free text was used. The following options are accepted reasons for using free text:

- API imported for export only
- API used in the fabrication of a drug exempt from DIN/NOC requirements (this includes API imported only for compounding by a practitioner, for the fabrication of a drug subject to section 37 of the Food and Drugs Act or other cases where a DIN or NOC is not required)
- DIN/NOC was issued after the date of last Table A update (2021-03-29) and the DPD entry is not available in the picklist. In these cases ensure to copy and paste the entry from the DPD in the free text field.

Inappropriate use of free text will cause a deficiency.

Column G - Final API Form Class

Select the Final API Form from the picklist (i.e. solid, liquid or gas), associated with the API listed in Column E.

Column H - Activity

Select the Activity you wish to apply for from the picklist. The activity selected will be associated with the API (Column E) and the API foreign building (Column I to L).

Column I to L – API foreign building name and address

Enter the API foreign building name and address using the picklist. To use the picklist start typing the name and the field will provide a suggestion based on what you have entered. The more you type, the closer you will get to the name you are entering. To see the foreign building names close to the suggested name you can select the down arrow to open the picklist. Once you select the foreign building

name, the form will restrict the address list to those addresses currently associated with the foreign building name. The picklist is populated by the foreign building profile in Health Canada licensing database.

If the entry you are looking for is not in the picklist, you can use the free text feature to populate the field. When using the free text feature, ensure the spelling of the foreign building name and address is accurate. Name and address discrepancies will cause the issuance of deficiency notice and delay the processing of your application.

Column M to Q – API foreign building GMP Status

Column M – Building complies with applicable GMP requirements sent out in Part C Division 2, FDR?

Select from the picklist, “Yes” or “exception”. “Exception” should only be selected in the following two scenarios: 1) API is used in a product that is part of the [Pilot Project for Selected Consumer Health Products](#) or, 2) API is on the [Atypical API List](#).

Column N – Date of last inspection

Enter the date of latest inspection conducted of the foreign building.

Column O – Inspection type

Select from the picklist the Inspection Type associated with the API foreign building in column I to L.

Column P – Specific authority which conducted inspection

Select from the picklist the authority which conducted the inspection indicated in Column N & O. The picklist choices reflect the list of inspecting authorities outlined in [GUI-0080](#).

Column Q – Has this building been issued a non-compliant rating in the last 5 years?

Select from the picklist to identify whether the API foreign building in column I to L has been issued a non-compliant rating in the last 5 years. Foreign buildings that are listed as currently being non-compliant on the Drug & Health Product Inspection Database ([DHPID](#)) are not to be listed on Table A, unless Health Canada has indicated otherwise. Listing a non-compliant foreign building on your Table A may lead to rejections. Instead you must submit application for such non-compliant foreign buildings using Section 5.2 of FMR-0033 along with new GMP evidence. If Health Canada deems the site compliant the building can be added to the API foreign building annex of the DEL.

Column R and S - Finished dosage form (FDF) drug foreign building name and address

These 2 columns are only required when the importer proposes to import a FDF drug fabricated outside of Canada. These columns are the information regarding the foreign building that fabricates the FDF drug. Please note that the Health Canada database requires that the FDF fabricator information you provide in these columns represent a foreign building listed on your DEL foreign building annex as an FDF fabricator. If the FDF drug fabricator you list in these two columns is not already listed on your DEL, in the same application you must include a request to add the foreign building to your DEL using FRM-0033. If the foreign building listed in these two columns is not in your DEL or in your application, your application will be deficient.

When filling these columns, enter the API foreign building name and address using the picklist. To use the picklist start typing the name and the field will provide a suggestion based on what you have entered. The more you type, the closer you will get to the name you are entering. To see the foreign building names close to the suggested name you can select the down arrow to open the picklist. Once

you select the foreign building name the form will restrict the address to those currently associated with the foreign building name. The picklist is populated by the foreign building profile in Health Canada licensing database.

If the entry you are looking for is not in the picklist, you can use the free text feature to populate the field. When using the free text feature, please ensure the spelling of the FDF foreign building is the same as it appear on your DEL's Foreign Building Annex or your application to add the FDF foreign building to your DEL. Name and address discrepancies will cause the issuance of deficiency notice and delay the processing of your application.

Column T - DIN(s) associated with API

Enter the DIN(s) associated with the API listed in Column E.

Note: When entering multiple DINs you could enter them in separate rows or in one row with a comma to delineate the DINs. All Dins must include all 8 digits including the zeros, if the DINs entered in this column are not delineated clearly or do not each have 8 digits, a deficiency notice will be issued.

Column U - API Class

Refers to whether the API for use at the foreign building listed in Column I to L will be used in the fabrication of a human drug, veterinary drug or both. Use the picklist to select the appropriate option.

Column V - Category of Drug

Select from the picklist the category of drug (API or List A API) that corresponds to the API entered in Column E.

4 Filling Table A for various application type

When filling Table A, regardless of the application type, you must submit one separate Table A per domestic building. This applies to you if you have multiple buildings from which you import drugs into Canada. As an example, as importer you may have 2 buildings from where you import drug, one in Western Canada and one in eastern Canada. If you wish to add an API foreign building for both domestic site, you will have to submit 2 distinct Table A, one for the eastern building and one for the western building.



When reviewing the requirements for each application type below, please note that as indicated in Section 3 Table A Columns, Column R & S are not always required. Each section is written as if these columns are required for simplicity, but they are only required when applicable (i.e. when the drug imported is a FDF drug).



Entering multiple rows for the same foreign building

When entering information into Table A there may be lines that only vary by the API name, final API form, DIN and/or category of drug. The reason for the Change Request you enter in column A should be the same for all rows, related to a specific API foreign building.

For example if adding a new API foreign building with 3 APIs, all three lines should have the “Change Request” identified as “add foreign building”. However, adding those same 3 APIs to an existing API foreign building, then the “Change Request” would be identified as “Add API”.

To make entering information in Table A easier, it is important to note that once a line is added from row 4 using the row 3 button, that row 4 remains populated. This allows you to update the API name, final API form, DIN and/or Category of drug without having to re-enter all the information.

4.1 Instructions to apply for new or initial API foreign building annex

As described in Section 15 of [GUI-0002](#), an importer’s DEL should include one API Foreign Building Annex for each Canadian building importing drugs. When applying to request a new API Foreign Building Annex (e.g. when applying for a new DEL, when applying to add a new Canadian building for import, or other scenarios) the application must include a FRM-0033 with a filled and signed section 5.1 and a Table A. In Column A of Table A select the change type “New API foreign building annex” and then enter the required information in every column as applicable, except column B and C.

If the application is for more than one Canadian importing building, the application must contain one Table A per importing domestic building.

4.2 Instructions for Amending an existing DEL

When filling Table A to amend your API Foreign Building Annex, do not submit a comprehensive Table A. Only submit a Table A that indicates the changes you wish to make to your API foreign building Annex or information you want to update. You can include as many changes as required in a single application including changes affecting more than one foreign building.

Adding an API Foreign Building

Select “Add foreign building” in Column A, and then enter the required information in every column as applicable.

Removing an API Foreign Building

Select “Remove foreign building” in Column A and enter the required information in columns B-D and I-L.

Changing of an API foreign building name/address

To change the API foreign building name and/or address enter the required information as follows:



When submitting API foreign building name/address please only send one change per application to avoid any confusion as to which change applies to which existing foreign building.

- For the old foreign building name/ address, in Column A select “Name/address change – old info” and enter the required information in Columns B-D and I-L.
- For the new foreign building name/ address, in Column A select “Name/address change – new info” and enter the required information in Columns B-D and I-L.

Activity addition for a API foreign building

In Column A select “Activity Addition” and then enter the required information in column B-L, T (as applicable) and U-V.

Activity removal for a API foreign building

In Column A select “Activity Removal” and then enter the required information in column B-D, and H-L and V.

Adding an API

In Column A select “Add API” and then enter the required information in Columns B-L, T (as applicable) and U-V.

Removing an API

In Column A select “Remove API” and then enter the required information in Columns B -L and U-V.

5 Questions

If you have questions regarding these instructions, please do not hesitate to contact Establishment Licencing (hc.del.questions-leppp.sc@canada.ca) for assistance.