Central Administration for Pharmaceutical Products
General Administration of Human Pharmaceuticals Registration
Administration of Technical Affairs for Human Pharmaceuticals

Notice to Applicant

Guidance on submission of Active Pharmaceutical Ingredients for Evaluation of Application (Listing of API / Using Listed API)

Year 2023

Code: EDREX: NP. CAPP.060
Version No: 1
Issue Date: 16 April 2023
Effective date (if needed): 16 April 2023

Scope:

This guidance applies for any API used in the manufacturing of different pharmaceutical products whether for application of Listing of Active Pharmaceutical Ingredient or Using Listed Active Pharmaceutical Ingredient.

Objective:

This guidance aims to provide applicants with the documents and information required for preparing and submitting the files for evaluation of (Listing of Active Pharmaceutical Ingredient or Using listed Active Pharmaceutical Ingredient) according to "*Decision of chairman of Egyptian Drug Authority no. 213/2023 and EDA Arrangement guidance of API listing for human medicinal products*".

It should be noted that Egyptian Drug Authority has the right to request any further information or documents, with a commitment that such requests are justifiable, and will be for the purpose of ensuring quality, safety and efficacy of the submitted product.

Applicants:

Applicants are classified according to:

A) Applicant for Listing of Active Pharmaceutical Ingredient which categorized as:

1. *Egyptian API Manufacturer. (Code # **A.1**)*
2. *Imported API Manufacturer. (Code # **A.2**)*
3. *Marketing Authorization Holder of Finished pharmaceutical product. (Code # **A.3**)*

B) Users of approved API listed by:

1. *Egyptian API Manufacturer. (Code # **B.1**)*
2. *Imported API Manufacturer. (Code # **B.2**)*
3. *Marketing Authorization Holder of Finished pharmaceutical product. (Code # **B.3**)*

Privilege(s) of beneficiaries:

The applicant **(A.3)** or users **(B.1, B.2 and B.3**) can get Privileges (*check table 1*) according to *"EDA Arrangement guidance of API listing for human medicinal products*".

Privileges:

1. Applying for Line Extension registration for the same active substance without adhering to the pharmaceutical dosage form specified in the similar box.
2. Applying the Fast Track system to submit the product dossier for registration or re-registration.
3. Additional grace period of 3 months to be added to the original deadline to complete the registration / re-registration procedures.

4. Modifying the batches release system in case of addition / change of the API supplier; where submission of stability study is the condition for FPP release instead of approving the stability study.

Table 1 :(Privilege(s) of beneficiaries)

	Applicant A.3	**User B.1**	**User B.2**	**User B.3**
Privilege(s)	*Select **2 privileges** from categories (1– 4)*	Get **All** privileges	*Select **2 privileges** from categories (2– 4)*	*Select **1 privilege** from categories (2– 4)*

Table 2: Required Documents:

Item No.	**Required Documents**	**Application of Listing API**	**Application of Using Listed API**
1	**Application Form** *(On applicant letterhead signed, stamped and dated)* ***(Attached: Template #1)***	**R**	**R**
2	**Action Letter** *(In case of Under-Registration products)* ***OR*** **Registration Certificate** *(In case of Registered products)*	**R** *(Only for Applicant A.3)*	**R**
3	**Name approval** *(In case of Under-Registration products)* ***OR*** **Registration Certificate** *(In case of Registered products)*	**R** *(Only for Applicant A.3)*	**R**
4	**Fees Payment Receipt**	**R** *(Only for non-previously approved S-Part Quality file)*	**R**
5	**Copy of Quality Approval of S-part**	**R** *(Only for Applicant A.3; for previously approved S-Part Quality file)*	**NR**
6	**Drug Master File (Including the Restricted Part)** *From the API Manufacturer (For Each API).* **- For details, please refer to this section in the quality module submission guidance, on the following link:** https://drive.google.com/file/d/1M_ew9dDDgdyod61r7Md3wrppEftC7S4Y/view?usp=sharing	**R** *(Only for non-previously approved S-Part Quality file)*	**N.R**

7	***Letter of access from the supplier***. *Link for editable Letter of authorization (access) Template:* https://docs.google.com/document/d/16OKC9Qcd1LByiJm1dQy97KZx3k1DwZmg/edit	**R** *(Only for non-previously approved S-Part Quality file)*	**R**
8	**Privilege(s) Declaration letter:** ***(Attached: Template #3)***	**R** *(Only if the applicant is MAH (A.3))*	**R**

Notes:

- **Fees Payment Receipt:** 7,000 L.E (for non-previously approved S-Part Quality file).
- **Fees Payment Receipt:** 1,000 L.E (for Users of approved API listed).

- **Abbreviations**
  - **R :** The Document is required.
  - **NR :** The Document is Not Required.

Documents naming, file preparation and arrangement

1- All ***Templates*** :to be filled by the Applicant company on the Applicant's letter head signed and stamped by the applicant company , then attached as an ***Adobe Acrobat Document (.pdf)***
-Link for editable copies of the templates:
https://docs.google.com/document/d/1NjQd2HRtlkkXWucZo7mqcHCKSsJbR7iM/edit?usp=share_link&ouid=111862349084529780102&rtpof=true&sd=true

2- All items from (1 to 8): *(if applicable)*

Documents should be submitted in form of separate ***Adobe Acrobat Document (.pdf)***

Template #1

Application Form

Application Form for Listing of Active Pharmaceutical Ingredient/Using listed Active Pharmaceutical Ingredient.

Type of Application	☐ **New** (*for applicant of API listing*) ☐☐**Renewal** (*for applicant of API listing*) ☐ **Variations** (*for applicant of API listing*) ☐ **User**
Active Ingredient(s): (*Including salts, hydrate …*)	
API DMF holder Name	
API Manufacturing Site Name	
DMF version number:	Applicant Part:…… Restricted Part:……
API Reference	*(Pharmacopeial Or in-house).*
Finished pharmaceutical product name, *if applicable* (Including strength and dosage form)	
Applicant's Status: **(***Applicant may be A or B***)**	*A- Listing applicant:* ☐ **Egyptian API Manufacturer.** **Name/ address :……** **Imported API Manufacturer.** **Name/ address :……** ☐ **Marketing Authorization Holder of Finished pharmaceutical product.** **Name/ address :……** *B- Users of Approved API in the EDA list.* **Name/ address :……** **Using approved API listed by:** ☐ **Egyptian API Manufacturer.**

	Name/ address :…… ☐ **Imported API Manufacturer.** **Name/ address :……** ☐ **Marketing Authorization Holder of FPP.** **Name/ address :……**
Privilege(s): *(Selected by the Marketing Authorization Holder of FPP or Users according to EDA Arrangement guide of API listing).*	☐ Line Extension registration for the same API without adhering to the pharmaceutical form specified in the similar box. ☐ Fast Track system to submit the product file for registration or re-registration. ☐ Additional grace period of 3 months to be added to the original deadline to complete the registration / re-registration procedures. ☐ Modifying the batches release system in case of addition / change of the API supplier; where submission of stability study is a condition for release instead of approving the stability study.
Applicant Company Representative	
Name:	
Telephone number:	
E-mail:	

Registration Manager

Name:
Signature:
Date:

Company Stamp

Template #2

Privilege(s) Declaration letter:

Applicant Company:	This section to be filled by the Applicant company
Trade Name:	This section to be filled by the Applicant company
Generic Name(s) + Strength(s):	This section to be filled by the Applicant company
Dosage Form:	This section to be filled by the Applicant company

Requested Privilege(s)
□ Applying for Line Extension registration for the same active substance without adhering to the pharmaceutical form specified in the similar box.
□ Applying the Fast Track system to submit the product file for registration or re-registration.
□ Additional grace period of 3 months to be added to the original deadline to complete the registration / re-registration procedures.
□ Modifying the batches release system in case of addition / change of the API supplier; where submission of stability study is a condition for release instead of approving the stability study.

Applicant Company Signature, Date & Stamp:

For privileges selection:

Please refer to *table 1 of Privilege(s)of beneficiaries* in submission guidance of Evaluation of application of (Listing of Active Pharmaceutical ingredients/ Using listed Active Pharmaceutical Ingredients).