Annex 4
to the Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-Registration) and for Expert Evaluation of Materials about Introduction of Changes to Registration Materials during the Validity Period of Registration Certificate (item 4 of section IV)

REGISTRATION FORM
for Active Pharmaceutical Ingredient Which is Submitted for State Registration (Re-Registration)

Date of submission «___» _____ 20__	№ _____

Trade (or proprietary) name of API (if available)	
Name of API *	
Applicant	
Applicant's representative (person authorized to act on behalf of the applicant)	
***** Only one name should be given in the following order of priority: INN (accompanied by its salt or hydrate form, if necessary), SPhU, European Pharmacopoeia, common name, scientific (chemical) name.	

I hereby ensure the validity and hold responsibility for the information contained in submitted materials of registration dossier.

I agree that, if materials of registration dossier have not been submitted within three months after the Center's receipt of the MoH letter of referral, the application for state registration (re-registration) of this API shall be revoked.

This is also to confirm that all envisaged fees will be paid according to the legislation requirements.

☐ Please attach letter of authorization for communication/signing on behalf of the applicant (subitem 3.1, item 3 of this Annex).

On behalf of the applicant	_____ (signature) _____ (name)

Seal	_____ (position)

1. REGISTRATION FORM PARTICULARS

1.1 Technological form (presentation) (liquid, powder, granules, pellets, etc.)

1.2. Container, including description of material from which it is made (use current list of standard terms of the State Pharmacopoeia of Ukraine or European Pharmacopoeia) **For each type of pack give:** 1.2.1. Package size(s) 1.2.2. Proposed shelf life 1.2.3. Proposed interval for repeated control (if established) 1.2.4. Proposed storage conditions

1.3. Applicant (holder of registration certificate)/contact person

1.3.1. Applicant (holder of registration certificate) (for domestic applicants – in Ukrainian, for foreign applicants - in Ukrainian and English):	
Name of legal person or full name of physical person–entrepreneur	
Location of legal person or address of physical person–entrepreneur	
Country	
Tel./fax	
e-mail	

1.3.2. Applicant's representative (authorized person to act on behalf of the applicant):	
Full name of authorized person to represent the	

applicant	
Name of legal person or full name of physical person–entrepreneur	
Location of legal person or address of physical person–entrepreneur	
Country	
Tel./fax	
e-mail	
☐ Please attach a letter of authorization (subitem 3.1, item 3 of this Annex).	

1.4. Manufacturers

1.4.1. Manufacturer responsible for batch release of API (for domestic applicants – in Ukrainian, for foreign applicants - in Ukrainian and English):	
Name of legal person or full name of physical person–entrepreneur	
Location of conducting activity	
Country	
Tel./fax	
e-mail	

1.4.2. Manufacturer(s) and manufacturing sites (for domestic applicants – in Ukrainian, for foreign ones - in Ukrainian and English). All manufacturing sites involved in manufacturing process of each source of API or active substance including sites, where quality/in-process control takes place, shall be specified.	
Substance	
Name of legal person or full name of physical person–entrepreneur (of the manufacturer)	
Location of conducting activity	
Country	

Tel./fax	
e-mail	

Brief description of manufacturing stages performed at manufacturing site

Has a Ph.Eur. Certificate of suitability been issued for this API?

□ No □ Yes

If yes:

□ Attach a copy of certificate of suitability (subitem 3.3 item 3 of this Annex).

Is a Master File to be used for this API?

□ No □ Yes

If yes:

□ Attach letter of access to master file (subitem 3.2, item 3 of this Annex).

Have the materials of animal and/or human origin been used in the manufacturing process of API?

□ No □ Yes

□ If a Ph. Eur. certificate of suitability for TSE or a document of veterinary control authorities of the country of origin of the raw materials concerning registered TSE cases in the country (based on results of clinical and laboratory control) is available, attach it in subitem 3.3, item 3 of this Annex.

1.5. Does API contain or consist of Genetically Modified Organisms (GMO)?

□ No □Yes

If yes, does API comply with established requirements?

Tick the necessary

□ No □Yes

2. Other information

2.1. Is API protected by patents for invention, useful model or production prototype, which are also valid in Ukraine?

□ No □ Yes

If yes:

Patent number	Date of issue	Valid till	Patent holder

2.2. Is the trade mark protected in Ukraine?

□ No □ Yes

If yes:

Document number	Date of issue	Valid till	Document holder

3. APPENDED DOCUMENTS (in case of registration)

□ 3.1. Letter of authorization for communication/signing documents on behalf of the applicant (registration certificate holder).

□ 3.2.Copy of license for large-scale manufacturing of API issued according to the manufacturer national legislation (if available).

□ 3.3. Letter(s) of access to API Master File(s) from its holder or copy of Ph. Eur. Certificate(s) of Suitability (if available).

□ 3.4. European Pharmacopoeia certificate of suitability for TSE or a document issued by veterinary surveillance authority of the country of origin of the raw materials concerning registered TSE cases (if any) (based on results of clinical and laboratory control) in the country.

{Annex 4 in wording of MoH Ukraine Order №460 as of 23.07.2015}