

DG Inspection/Authorisations Division/Specially Regulated Substances Entity/RD 12.04.1974 Team

Send BY POST to:

Federal Agency for Medicines and Health Products DG Inspection – Authorisations Division – Substances RD 12.04.1974 Team Avenue Galilée 5/03 1210 BRUSSELS

Or

Send BY EMAIL to: substances HAA@fagg-afmps.be

Only when provided with the correct <u>qualified</u> electronic signatures (NO SCANS).

Application of art. 1§4 of the Royal Decree dated 12 April 1974 regarding some operations in connection with substances with hormonal, anti-hormonal, anabolic, beta-adrenergic, anti-infectious, anti-parasitic and anti-inflammatory effects, last revised by the R.D. dated 4 February 2002 (B.S. dated 28 February 2002).

CHANGES to the information provided on the licence for substances R.D. 12.04.1974							
Licer	nsee name:				ence nber:	Indicate as appropriate: NL/FR	
E-mail contact person for the license:							
Information for invoice (contact details for mailing the invoice).		Contact person					
		E-mail					
		Address					
		Company number					
		Extra information to be mentioned on invoice					
Type of change:							
A.	Name and/or addres	s of licensee:	Old details:		New	details:	
Please enclose official proof.		proof.					

В.	Statutory or legally responsible person:	Name of former responsible person:		Name o	Name of new responsible person:	
	Please enclose official proof.			Signatu	ire:	
C.	Person charged with the responsibility for performing the obligations determined by the aforementioned decree:	Name of former responsible person:			Name of new responsible person:	
	Signature of the statutory or legally responsible person for approval:				Signature:	
D.	Laboratory manager:	Name of former laboratory manager:		Name o	Name of new laboratory manager:	
	Signature of the statutory or legally responsible person for approval:				Hereby declares to only use the substances for analytical and/or scientific purposes within the lab Signature:	
E.	Extension/change of the type of activities: Note: all activities with medicines regulated by a Manufacturing and Importation Authorisation (« MIA ») or Wholesale Distributor Authorisation (« WDA ») are exempted. API's are not exempted.	☐ Import ☐ Manufacturing of raw mate (not of medicine) ☐ Export ☐ Offering for sale/ Sale		terials	☐ Possession ☐ Acquiring by payment or at no cost	
F.	Activity sites: ☐ Change of the current address of the activity site: ☐ Addition of an extra activity site ☐ Deletion of an activity site	Address:				



G.	Expansion of the licensed substances:	Substance name:	CAS number:	Application/justification:
	In case of insufficient space, you may add an appendix to the application, to list the relevant substances and			
	their corresponding CAS-number.			

For B, C and D (SIGNATURE REQUIRED):

1. By POST, only if the original form has been signed (no copies or scans) to:

Federal Agency for Medicines and Health Products
DG Inspection – Authorisations Division - Substances RD 12.04.1974 Team
Avenue Galilée 5/03
1120 BRUSSELS

Or

2. By E-MAIL, ONLY if the form has been provided with ALL the necessary qualified electronic signatures AFTER it has been completed in full, to: substances HAA@fagq-afmps.be

(signature via ID card or see https://economie.fgov.be/fr/themes/line/commerce-electronique/signature-electronique-et).

Company tokens are usually not qualified electronic signatures and may be considered inadmissible.

The signature can be added by double-clicking on the signature field. Once signatures have been added, it is no longer permitted to edit the form, so please complete the form in full before adding the signatures. If the form does need to be changed again, the signatures must be re-applied. Otherwise, the application will be inadmissible.

For A, E, F, G and H (no signature required), this may also be returned by e-mail to a responsible person (listed on the licence) or submitted by a third party if they are listed in the cc as a responsible party to: substances HAA@fagg-afmps.be

The fee amount is indexed annually and can be viewed at any time on the FAMHP website.

