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 qualified 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				
Licensee name:			**Licence number:**	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 address of licensee:** **Please enclose official proof.**	Old details:	New details:	

B.	**Statutory or legally responsible person:** **Please enclose official proof.**	Name of former responsible person:	Name of new responsible person: Signature:	
C.	**Person charged with the responsibility for performing the obligations determined by the aforementioned decree:** **Signature of the statutory or legally responsible person for approval:**	Name of former responsible person:	Name of new responsible person: Signature:	
D.	**Laboratory manager:** **Signature of the statutory or legally responsible person for approval:**	Name of former laboratory manager:	Name of new laboratory manager: **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 ☐ Export ☐ Transport	☐ Manufacturing of raw materials (not of medicine) ☐ Offering for sale/ Sale	☑ 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:** In case of insufficient space, you may add an appendix to the application, to list the relevant substances and their corresponding CAS-number.	Substance name:	CAS number:	Application/justification:

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
   1210 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@fagg-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.