22 October 2020

Administration and Corporate Management Division

EMA/501697/2020

**EMEA ASMF number request form**

***(< FROM ACTIVE SUBSTANCE MASTER FILE HOLDER ON HEADED PAPER>)***

From:<ASMF Holder name>

<ASMF Holder address>

<ASMF Holder <Post code> Town>

<ASMF Holder Country>

<ASMF Holder **email address**>

Subject: Submission of request for **EMEA/ASMF/XXXXX number**

Dear Sir or Madam:

We would like to obtain an EMEA/ASMF/xxxxx number for our upcoming ASMF submission in relation to the following procedure:

|  |  |
| --- | --- |
| Active Substance Name  Allocated procedure number(s)  Name of Medicinal Product(s) the ASMF is related to  (Intended) Submission date of the marketing authorisation application (if known) | <INN, common name> (+ salt/water content when applicable)  <EMEA/H/C/product reference number/procedure reference>  <Product 1>  <Product 2>  <Product 3>  <DD/MM/YYYY> |

This request form should be used for an Active Substance Master File to be assessed through the Centralised procedure only.

Please note that an EMEA/ASMF number is not recommended in case you also intend to register your ASMF in the Decentralised and/or Mutual Recognition Procedures. In this case, please apply for an EU/ASMF number, which can be used in Centralised, Mutual Recognition and Decentralised Procedures. (<http://esubmission.ema.europa.eu/eASMF/index.htm>)

**Mandatory administrative details for obtaining an EMEA ASMF number**

Where the ASMF holder already holds an ASMF that has been assigned an EMEA ASMF reference number and wishes to register another ASMF for the same active substance, e.g. a substantially different route of synthesis (see Annex 1 Assignment of a new ASMF Reference Number), this should also be clearly stated in the Additional information field.

|  |  |
| --- | --- |
| ASMF Holder | <ASMF Holder name>  <ASMF Holder’s address>  <ASMF Holder’s email address> |
| Active Substance Manufacturer´s internal API code (if applicable) |  |
| ASMF holder’s version (as included in the future submission) | Applicants part:  Version [version number]/date (dd-mm-yyyy)  Restricted part:  Version [version number]/date (dd-mm-yyyy) |

|  |  |
| --- | --- |
| Additional information (as applicable, e.g. different route of synthesis, grade) **[[1]](#footnote-1)** |  |

I hereby declare that an EU ASMF number under ASMF worksharing procedure has not been requested from either the EMA or from a National Competent Authority for this ASMF dossier[[2]](#footnote-2).

Yours faithfully,

<Signature of authorised contact person>

<Name, address and position in company>

<email address >

To submit your request, raise a ticket via [EMA Service Desk](https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/23/create/30), using the Question option. The Type of question to be selected is “Request for high-level procedure or ASMF number” followed by sub-option “ASMF number” and attaching this form.

If you do not have an EMA Account, you may create one via the [EMA Account Management portal](https://register.ema.europa.eu/identityiq/login.jsf).

1. May warrant the ASMF holder a new EMEA/ASMF number. [↑](#footnote-ref-1)
2. Condition necessary for the eligibility of the ASMF to receive an EMEA/ASMF number. [↑](#footnote-ref-2)