15 July 2019

EMA/624104/2019

Human Medicines Development and Evaluation

**GMO CONSULTATION REQUEST FORM**

(Not required in the CA has undertaken an overall confidentiality agreement with the European Medicines Agency)

To be returned as signed PDF via email by <date = day 9 of procedure >

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| --- | --- | --- | --- | --- | --- |
| **DATE:** | Name and email | | **EMA procedure:** | **EMEA/H/C/xxxx** | |
| TO: | <PL name>  (European Medicines Agency)  <PL>@ema.europa.eu | | PHONE: | +31-xxxx | |
| FROM: |  | | PHONE: |  | |
| RE: | Request for consultation for the evaluation for a Marketing Authorisation Application for the medicinal product for human use <PRODUCT NAME> containing or consisting of a GMO | | | | |
| Number of Pages (including cover sheet): 1 | | | | | |
| Name of the Competent Authority, Country, full contact details and e-mail: | | *Provide full contact details: name, address, phone, fax, email.* | | | |
| Statement on Confidentiality  The undersigned undertakes with respect to the assessment of <PRODUCT NAME> and its risk to environment, as amended, to respect the confidentiality provision laid down in Article 76 of Regulation 726/2004. This includes the obligation to keep strictly confidential data in relation to the submission of the dossier, the name of the applicant and the product, all data contained in the dossier as well as all assessment reports relating to the product. The undersigned acknowledges that it is bound not to disclose any of the aforementioned information to any third party or the public during the evaluation of the application and that information to the public will only be made available as part of the European Public Assessment Report (EPAR) following the Commission Decision for the Marketing Authorisation.  (signature)  On behalf of the Competent Authority | | | | |