**Application for authorisation of a novel tobacco product**

according to § 10a of the Tobacco and Non-Smoking Protection Act (BGBl. No. 431/1995 as amended) and the

Ordinance on the Approval of Novel Tobacco Products (NTZulV) (BGBl. II No. 42/2017 as amended)

**Authorisation applicant (= person placing the product on the market)**

Name/Company:

Address:

Contact (phone, e-mail, fax):

Proof of trade licence/authorisation: ☐ Enclosed ☐ will be submitted subsequently

**Manufacturer**

Name/Company:

Address:

Place of manufacture, if different:

**Product information**

Product (in similar form) already

available in Austria before 20.05.2014: ☐ Yes ☐ No

Intended trade name (type, brand name, variety):

Description:

Purpose/Application area:

**Approval in another EU member state**

 ☐ Requested ☐ Yes, already admitted in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ☐ No

If yes; registration documents incl. notification of admission

☐ enclosed ☐ to be submitted subsequently

Reference holdings (where available):

|  |  |  |  |
| --- | --- | --- | --- |
| **Required documents**  | enclosed  | will be submitted subsequently | not applicable |
| Operating instructions |[ ] [ ] [ ]
| Technical specifications  |[ ] [ ] [ ]
| Listing of all ingredients and additives  |[ ] [ ] [ ]
| Listing of emissions  |[ ] [ ] [ ]
| Information on material properties  |[ ] [ ] [ ]
| Information on product safety and quality assurance and the measures envisaged for this purpose  |[ ] [ ] [ ]
| Relevant recent opinions, test reports or scientific work  |[ ] [ ] [ ]
| Scientific studies on toxicity, addiction potential and attractiveness  |[ ] [ ] [ ]
| Studies, summaries thereof and market research on the preferences of different consumer groups  |[ ] [ ] [ ]
| Risk-benefit analysis, expected effects on the phasing-out/starting of tobacco consumption, expected consumer perception |[ ] [ ] [ ]
| Sample and label |[ ] [ ] [ ]

**Note:**

The Austrian Agency for Food Safety GmbH may require additional documentation if it considers the information to be incomplete.

The fee for the approval of novel tobacco products according to § 10a TNRSG amounts to 7,953.-- Euro and has to be paid to AGES at the latest four weeks after application.

If an application for approval is withdrawn within four weeks of the application being submitted, or if the applicant does not comply with a possible order for improvement or does not comply in time and the application is therefore rejected, 10% of the approval fee must be paid. If the application is withdrawn only after four weeks have elapsed since the application was filed, or if an application for admission is rejected, the entire admission fee must be paid.

Place, Date Signature