To: **Complementary Health Products Branch**
Health Products Regulation Group
Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

Product name 所申请的中成药产品名称：_____

(English / Chinese)（英文/中文）：_____

Brand name 商标名：_____ Dosage form 剂型：_____

Manufacturer 所申请的中成药成品的生产商：_____

INFORMATION REQUIRED FOR FERMENTED SUBSTANCE(S) IN CPM
中成药中所含的发酵成份的信息资料

A. Please fill up the following 请填写以下信息（信息需由生产发酵成份的厂商提供）：

I. Fermented Substance(s) (e.g. Cordyceps, Red Yeast Rice)发酵成份（如虫草菌丝体，红曲）:
1. Species (Please include strain identification report, except for *Monascus pupureus*) 发酵成份所使用的菌种的名称（请附上菌种的鉴定报告，红曲霉菌种不需要提交）
2. Source(s), including the name(s) and address(es) of the manufacturer(s) 发酵成份的来源，请指明其生产商的名称和地址

B. Please fill up and attach the following 请填写以下信息:

I. Fermented Substance(s):发酵成份的外观描述及化学特性	Name of Document(s) Attached 请呈交文件，并在此注明所附文件名
Please submit the specifications and Certificate of Analysis (COA) of the fermented substance(s), including description of physical characteristics such as colour, texture and quantity of active constituents (e.g. adenosine ≥XX%) 请呈交发酵物的规格及检验报告，需注明其物理性状，如颜色和质地等，及其有效化学组分的含量要求（如腺苷≥XX%）	
II. Details of Manufacturing Process of Fermented Substance(s):发酵的详细工艺过程	Name of Document(s) Attached 请呈交文件，并在此注明所附文件名
Please submit the manufacturing process in the form of flowchart(s), and indicate the type of fermentation (e.g. liquid/solid) and conditions used (e.g. temperature, pressure, humidity) 请呈交发酵的工艺流程图，并指明发酵的类型（如固体/液体），以及发酵的条件（如温度、压力、湿度）	
2. Manufacturer's licence and GMP Certificate, where applicable 生产发酵物的厂商的生产许可证及 GMP 证书，如有	

C. Please confirm the following and attach the required details where applicable
请确认并根据要求附加详细资料：

I. Details of Manufacturing Process of Fermented Substances: 发酵的详细生产工艺	Yes/No 有/没有	If yes, details to be submitted 如有，请提交相关资料
1. Animal-derived materials used, if any (e.g. animal lipids in culture media) 是否使用来源于动物的成份（如以动物油脂作为培养基），如有		1. List of animal-derived materials 列出使用的来源于动物的成份 2. If ruminant-derived material is used, please attach CPMF9.6* 如含反刍动物成份，需填表格 CPMF9.6*
2. Impurities / By-products produced during manufacturing, if any 杂质/发酵过程的副产品，如有		Allowable impurities / by-products limits / specifications 允许的杂质/发酵过程的副产品的限量/规格
3. Solvents / chemicals used for purification, if any 是否使用溶剂/化学品进行提纯，如有		List of solvents / chemicals 列明所用的溶剂/化学品名
4. Solvents / chemicals used for extraction, if any 是否使用溶剂/化学品进行提取		List of solvents / chemicals 列明所用的溶剂/化学品名
5. Hazardous additives, e.g. bleaching agents used during manufacturing 是否使用了有害的添加剂，如发酵过程中使用漂白剂		List of hazardous additives and the allowable residual limits 列明该添加剂及允许的限量
6. Residues, if any 残留物，如有		Allowable residues limits / specifications 允许的残留物的限量/规格

*CPMF9.6_TSE undertaking form, to be filled up by the local applicant, can be downloaded from the HSA website. 表格 CPMF9.6 可由卫生科学局网站下载，并需由本地的产品申请人填写。

D. Additional Information 其它附加资料：

Details 详细资料	Yes/No 有/没有	If yes, Name of Document(s) Attached 如有，请呈交文件，并在此注明所附文件名
1. Information on system for quality control (e.g. SOPs or workflows to avoid strain mutation, degeneration and contamination in the fermented substance) 质量控制的相关资料（如：避免菌种变异、衰退及污染的标准作业程序或流程）		
2. COA of the fermented substance showing testing of other by-products or toxic substances, 发酵物中可能产生的副产品或有毒物质的检验报告		
3. Composition of culture media used in manufacturing process 生产过程中所使用的培养基的组成成分		

E. Manufacturer of Fermented Substances 生产发酵物厂商的详细资料：

I hereby declare that the above information on this form is current and correct. 我声明以上所提供的信息是完全真实并正确的。

Name 姓名：_____ Designation 职务：_____

Name and address of company 生产发酵物的厂商名称及地址：_____

_____

Tel 电话：_____ Fax 传真：_____ Date 日期：_____

Signature 签名：_____

F. Local Applicant 本地申请者的详细资料:

Should the above CPM product be listed by HSA, I shall report any changes to the above details to the Complementary Health Products Branch as soon as possible. 以上产品若经卫生科学局登记后有任何变更，我会尽快通知辅助医疗保健产品组.

Name 本地申请人的姓名：_____ Designation 职位：_____

Name of company: 本地申请公司的名称：_____

Tel 电话：_____ Fax 传真：_____ Date 日期：_____

Signature 申请人签名：_____