（八）再生医療等製品の再生医療等製品外国製造業者の認定の場合

動物用再生医療等製品再生医療等製品等外国製造業者認定申請書

Application for accreditation of foreign animal regenerative, cellular therapy and gene therapy products manufacturer

年　　月　　日

Year Month Day

農林水産大臣　　殿

To Minister of Agriculture, Forestry and Fisheries

住所

Address

氏名　（法人にあっては、名称及び代表者の氏名）

Name　(Name and name of its representative in case of a corporation)

医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第 23 条の 24 第１項の規定により動物用再生医療等製品の再生医療等製品外国製造業者の認定を受けたいので、下記により申請します。

I hereby apply for the accreditation of the foreign animal regenerative, cellular therapy and gene therapy products manufacturer pursuant to Article 23-24, Paragraph 1 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, indicated following.

記

１　製造所の名称及び所在地

Name and location of the manufacturing establishment

２　受けようとする認定の区分

Accreditation categories in which the application is made

３　製造所の構造設備の概要

Outline of the buildings and facilities of the manufacturing establishment

４　製造所の責任者の氏名及び住所

Name and address of the person responsible for the manufacturing establishment

５　申請者（申請者が法人であるときは、薬事に関する業務に責任を有する役員を含む。）が法第５条第３号イからトまでに該当することの有無

Whether or not the applicant(if the applicant is a corporation, include the serving executive responsible for the services of pharmaceutical affairs) corresponds to Article 5, Item 3 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics

６　参考事項

Reference matters

（日本産業規格Ａ４）

(Japanese Industrial Standards Size A4)