様式第十八（第三十六条、第百三十七条の十九関係）
Form No.18 (related to Article 36 and Article 137—19)

収入印紙
revenue stamp

医　薬　品
医薬部外品　外国製造業者　認定申請書
再生医療等製品

Application for accreditation of foreign drug / quasi-drug / regenerative, cellular therapy and gene therapy products manufacturer

製造所の名称 Name of the manufacturing establishment		
製造所の所在地 Location of the manufacturing establishment		
認定の区分 Accreditation categories		
製造所の構造設備の概要 Outline of the buildings and facilities of the manufacturing establishment		
製造所の責任者 The person responsible for the manufacturing establishment	氏名 Name	
	住所 Address	

申請者（法人にあつては、薬事に関する業務に責任を有する役員を含む。）の欠格条項 Applicant's disqualifications (including those of the executives responsible for the services of pharmaceutical affairs in case of a corporation)	(1) 法第75条の4第１項の規定により認定を取り消され、取消しの日から３年を経過していない者 Applicant whose license was canceled pursuant to the provision of Article 75-4, Paragraph 1 and who is awaiting a lapse of 3 years from the date of said rescission	
	(2) 法第75条の5第１項の規定により登録を取り消され、取消しの日から３年を経過していない者 Applicant whose license was canceled pursuant to the provision of Article 75-5, Paragraph 1 and who is awaiting a lapse of 3 years from the date of said rescission	
	(3) 禁錮以上の刑に処せられ、その執行を終わり、又は執行を受けることがなくなつた後、３年を経過していない者 Applicant who has a history of a court sentence of imprisonment on severer punishment and has not passed 3 years since the execution was completed or no longer received	
	(4) 法、麻薬及び向精神薬取締法、毒物及び劇物取締法その他薬事に関する法令で政令で定めるもの又はこれに基づく処分に違反し、その違反行為があつた日から２年を経過していない者 Applicant who has a history of violation of Law, Narcotics and Psychotropics Control Law, Poisonous and Deleterious Substances Control Law or other laws and regulations related to pharmaceutical affairs specified by Cabinet Order and has not passed 2 years since its date of the disposition	
	(5) 麻薬、大麻、あへん又は覚醒剤の中毒者 Addict on narcotics, cannabis, opium or stimulant	
	(6) 精神の機能の障害により外国製造業者の業務を適正に行うに当たつて必要な認知、判断及び意思疎通を適切に行うことができない者 Applicant who cannot properly perform the necessary recognition, judgement and communication to perform the work of foreign manufacturers properly due to mental dysfunction	
	(7) 外国製造業者の業務を適切に行うことができる知識及び経験を有すると認められない者 Applicant who is not recognized as having knowledge and experience to properly carry out the work of foreign manufacturers	
備考 Remarks		

上記により、医　薬　品／医薬部外品／再生医療等製品　の外国製造業者の認定を申請します。

I hereby apply for the accreditation of the foreign drug / quasi-drug / regenerative, cellular therapy and gene

様式第十八から様式第二十までを次のように改める。