Form No. 21-2 (related to Article 37-2)

収入印紙 revenue stamp 医 薬 品 医薬部外品 外国製造業者 登録申請書

drug

Application for the registration of foreign

manufacturer quasi-drug

| 製  | 進   |   | の名称  |   |  |
|--|-----|---|--|---|--|
| Name of the manufacturing establishment<br>製造所の所在地   |     |   |  |   |  |
| Location of the manufacturing establishment  |     |   |  |   |  |
| 製造所の責任者  |     |   | 氏 名  |   |  |
| The person responsible for   |     |   | Name<br>住 所  |   |  |
| the manufacturing establishment  |     | stablishment  | Address  |   |  |
| атакн  |     | 法第75条の  |  | 取り消され、取消しの日から3年を経過して                      |  |
| 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<br>Applicant's disqualifications (including those of the executives responsible for the services of pharmaceutical affairs in case of a corporation) | (1) | いない者  | 1  |   |  |
|  |     |   | Applicant whose accreditation 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   |   |  |
|  |     |   |  | なり消され、取消しの日から3年を経過して                      |  |
|  | (-) | いない者  |  |   |  |
|  | (2) | Applicant whose registration 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   | 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<br>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<br>Addict on narcotics, cannabis, opium or stimulant                   |  |   |  |
|  |     |   |  | ii or stilluralit<br>終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  |  |   |  |
|  | (6) | Applicant who cannot properly perform the necessary recognition, judgement                |  |   |  |
|  |     |   | and communication to perform the work of foreign manufacturers properly due to mental dysfunction  |   |  |
|  |     | 大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   |  |   |  |
|  | (7) |   | who is not recognized as having knowledge and experience to  |   |  |
| H & ()   |     | properly c  | carry out the work of forei  |   |  |
| 備。    考  |     |   |  |   |  |
| Remarks  |     |   |  |   |  |
|  |     |   |  |   |  |

医 薬 品 医薬部外品の外国製造業者の登録を申請します。 上記により、

I hereby apply for the registration of the foreign

quasi-drug manufacturer indicated above.

年 月 日 Year Month Day

邦文

Japanese

住 所 Address

外国文

Foreign language

法人にあつては、主たる事務所の所在地 Location of the head office in case of a corporation.

邦文 Japanese

氏 名 Name

外国文

Foreign language

厚生労働大臣 殿 (法)

〈法人にあつては、名称及び代表者の氏名 Name and name of its representative in case of a corporation,

**一个工厂** 

To Minister of Health, Labour and Welfare

(注意)

(Notes)

1 用紙の大きさは、A4とすること。

Use paper of Japanese Industrial Standards Size A4.

2 この申請書は、正副2通提出すること。

Applicant should submit one original and one copy of it.

3 字は、墨、インク等を用い、邦文にあつては、楷書ではつきりと書くこと。

Fill in the form with clear writing with inks, etc.,.

4 収入印紙は、正本にのみ貼り、消印をしないこと。

Put revenue stamp only on the original and do not cancel it.

5 申請者の欠格条項の(1)欄から(7)欄までには、当該事実がないときは「なし」と記載し、あるときは、(1)欄及び(2)欄にあつてはその理由及び年月日を、(3)欄にあつてはその罪、刑、刑の確定年月日及びその執行を終わり、又は執行を受けることがなくなつた場合はその年月日を、(4)欄にあつてはその違反の事実及び違反した年月日を記載すること。

Describe "No" in each column of (1), (2), (3), (4), (5), (6) and (7) if an applicant doesn't meet any conditions of its disqualifications. If an applicant meets one or more conditions of its disqualifications, describe as below.

Column (1) and (2): The date (year, month, day) and its ground for the cancellation.

Column (3) : The date (year, month, day) of final judgment of the crime, sentence and

the date (year, month, day) of the completion of its execution.

Column (4) : The fact and the date (year, month, day) of its violation(s).