（注意）
(Note)

１　用紙の大きさは、Ａ４とすること。
Use paper of Japanese Industrial Standard Size A4.

２　字は、墨、インク等を用い、楷書ではつきりと書くこと。
Fill in the form with clear writing with inks etc.

３　製造業の許可若しくは登録区分又は医薬品等外国製造業者の認定若しくは登録区分欄については、第 25 条各項の各号、第 35 条各項の各号又は保管のみを行う製造所のいずれに該当するかを記載すること。

Identify in the column of “License or registration category of the manufacturer, accreditation or registration category of the foreign manufacturer” which category specified under each Paragraph of Article 25 or Article 35, or storage category of manufacturing establishment is applied.

４　製造業の許可若しくは登録番号及び年月日又は医薬品等外国製造業者の認定若しくは登録番号及び年月日欄については、法第 13 条第１項の許可、法第 13 条の３第１項の認定又は法第 13 条の２の２第１項若しくは法第 13 条の３の２第１項の登録を受けようとする者である場合は、許可、認定又は登録申請受付番号及び申請年月日を記載すること。

Identify in the column of “Number and date of the license or registration for the manufacturer, or of the accreditation or registration for the foreign manufacturer of drug, etc.” the receipt number and the date of the application for license, accreditation or registration, in case that applicant is going to have a license under Article 13, Paragraph 1 of the Act, an accreditation under Article 13-3, Paragraph 1 of the Act, or a registration under Article 13-2-2, Paragraph 1 or Article 13-3-2, Paragraph 1 of the Act.

５　調査を受けようとする製造工程の区分欄については、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十四条第八項に規定する医薬品又は医薬部外品の製造工程の区分を定める省令第２条各号に掲げる区分のいずれに該当するかを記載すること。また、製造品目数欄に申請区分に属する製造品目の数、製造販売業者数欄に当該製造品目に係る製造販売業者の数を記載すること。

Identify in the column of “Types of the manufacturing activities to be examined” which manufacturing type as provided in Article 2 of Ministerial Order specifying manufacturing types of drug or quasi-drug under Article 14, Paragraph 8 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics is applied. In addition, identify in the column of “Number of the product items” how many product items covered with the applied manufacturing type, and in the column of “Number of the marketing license holders in Japan” how many marketing license holders in Japan related to those product items.

６　独立行政法人医薬品医療機器総合機構理事長に申請する場合にあつては、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関係手数料令において定める適合性調査手数料を機構の口座に払い込んだことを証する書類の写しを裏面に貼付すること。

In case where the application is submitted to the Chief Executive of the Pharmaceuticals and Medical Devices Agency, affix a copy of the receipt for the remittance of examination fee, as provided in the Government Order on the fees related to the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, to the bank account of the agency.