Regulations for the Issuance and Administration of Controlled Drugs Prescription Licenses and Registration Licenses

(Amended Date:2013-11-08)

1.Full text of 18 articles promulgated and enforced by the Department of Health, Executive Yuan, Order No. 1001800702 on 22 November 2011
2.Full text of 18 articles amended and issued per 8 November 2013 Order No. Ministry-Shou-Shi-1021850245 of the Ministry of Health and Welfare; for enforcement from the date of issuance

Article 1 These Regulations are adopted pursuant to Article 7, paragraph 4, and Article 16, paragraph 5 of the Controlled Drugs Act ("the Act").

Article 2 A physician, dentist, veterinarian, or assistant veterinarian applying for issuanceof a controlled drug prescription license under Article 7, paragraph 1 of the Act shall submit the following documents with the application to the Food and Drug Administration (FDA), Ministry of Health and Welfare:
1. Controlled drug prescription license application.
2. One photocopy of the professional qualification certificate.
3. One photocopy of the practice license.

Article 3 The controlled drug prescription license shall record items including the prescriber's full name, date of birth, professional qualification certificate number, and the prescription license number.

Article 4 When there is any change to any of the items recorded on the controlled drug prescription license, within 15 days from the date of

occurrence of the change, a Controlled Drug Prescription License Amendment Registration Application, the documents in Article 2, subparagraphs 2 and 3, and the original copy of the original controlled drug prescription license shall be submitted to the FDA to carry out amendment registration.

Article 5 If the controlled drug prescription license is lost or damaged, the documents in Article 2 shall be submitted to the FDA with an application for re-issuance or replacement. If a prescription license that has been reported lost is subsequently recovered, it shall immediately be surrendered for cancelation.

Article 6 If the holder of a controlled drug prescription license dies, the FDA shall cancel the holder's controlled drug prescription license.

Article 7 If the professional qualification certificate or practice license is voided, revoked, or canceled, the FDA may void or revoke the holder's controlled drug prescription license.

Article 8 A holder of a controlled drug prescription license who will no longer administer schedule 1 to schedule 3controlled drugs may submit an Application for Surrender of Controlled Drug Prescription License and the original of the controlled drug prescription license to the FDA to carry out cancellation of the controlled drug prescription license.

Article 9 When a holder of a controlled drug prescription license is subject to a disposition suspending the writing of prescriptions for or suspending the

administration of controlled drugs, the holder shall immediately surrender the holder's controlled drug prescription license to the FDA, for return when the suspension period subsequently expires.

Article 10 An applicant for a controlled drug registration license shall submit one each of the following documents to the FDA with the application:
1. Controlled drug registration license.
2. Photocopy of the document granting permission for establishment of the institution or business:
(1)Medical institution: practice license.
(2) Pharmacy: pharmacy license.
(3) Pharmaceutical seller: pharmaceutical sales enterprise permission license.
(4) Pharmaceutical manufacturer: pharmaceutical manufacturer permission license.
(5) Veterinary medical institution: practice license.
(6) Livestock veterinary institution: document granting permission for establishment, with government accreditation.
(7) Veterinary medicine seller: veterinary medicine sales enterprise permit.
(8) Veterinary medicine manufacturer: document certifying factory registration, company registration, or business registration.
(9) Medical and educational research and testing institutions: document granting permission for establishment or other certifying document, with government accreditation.
3. Photocopy of the identity document of the responsible person of the institution or enterprise.
4. Photocopy of the qualification documents of controlled drug managers:

(1) Subparagraph 2, items 1 to 5: professional qualification certificate andpractice license.
(2) Subparagraph 2, items 6 to 8: professional qualification certificate and certificate of current employment.
(3) Subparagraph 2, item 9: national ID and certificate of current employment.

Article 11 Under any of the following circumstances, approval will be denied to an institution or enterprise applying for a controlled drug registration license:
1. The responsible person has previously violated the Act, resulting in any disposition, within the two years preceding the application, to void or revoke the controlled drug registration license of the institution or enterprise.
2. The responsible person or a controlled drug manager has previously violated the Narcotics Hazard Prevention Act, and has been indicted by a prosecutorial authority or found guilty by a court judgment. However, this shall not apply if the person has been found not guilty by a final and conclusive court judgment.

Article 12 The controlled drug registration license shall record items including the institution or enterprise's name, address, registration license number, name of the responsible person, names of controlled drug managers, professional category, business category, and issuance date.

Article 13 When there is any change to any of the items recorded on the controlled drug registration license, then in accordance with Article 16, paragraph 3 of the Act, within 15 days from the date of occurrence of the change, a Controlled

Drug Registration License Amendment Registration Application, the documents in Article 10, subparagraphs 2 to 4, and the original copy of the original controlled drug registration license shall be submitted to the FDA to carry out amendment registration.
When applying for registration of a change to the responsible person or a controlled drug manager, the status of the controlled drug record book entries shall be reported, and the controlled drug inventory and balance data shall be submitted therewith.

Article 14 If the controlled drug registration license is lost or damaged, the documents in Article 10 and the controlled drug inventory and balance data shall be submitted to the FDA with an application for re-issuance or replacement. If a registration license that has been reported lost is subsequently recovered, it shall immediately be surrendered for cancellation.

Article 15 If a holder of a controlled drug registration license will no longer engage in controlled drug business, then once the holder has reported the controlled drug record book entry status, and no longer has any remaining stock of controlled drugs, the holder shall submit an Application for Surrender of Controlled Drug Registration License, the controlled drug registration license, and the controlled drug inventory and balance data to the FDA to carry out cancellation of the controlled drug registration license.

Article 16 When the holder of a controlled drug registration license applies for permanent cessation of business or when the document granting

permission for establishment referred to in Article 10, subparagraph 2 is subject to a disposition of voidance or revocation, the holder shall report the status of the controlled drug record book entries, and submit therewith an Application for Surrender of Controlled Drug Registration License, the controlled drug registration license, and the controlled drug inventory and balance data to the FDA to carry out cancellation of the controlled drug registration license. If the controlled drug registration license is not duly surrendered for cancellation, the FDA shall cancel it.

Article 17 When the holder of a controlled drug registration license applies for suspension of business or is subject to a disposition of suspension of business, the holder shall report the status of the controlled drug record book entries, and submit therewith a written statement and the controlled drug inventory and balance data, to the FDA for recordation, and promptly submit the controlled drug registration license to the local competent authority, for return when resumption of business is subsequently approved.

Article 18 These Regulations shall be enforced from the date of issuance.