

Organization Act of the Food and Drug

Administration, Ministry of Health and Welfare

(Date: 2013.06.19)

1. Promulgated on June 3, 2009.
2. Full text including 7 articles amended and promulgated on June 19, 2013 on presidential order Taitong (1) number 10200113961.

Article 1 The Ministry of Health and Welfare shall establish the Food and Drug Administration (hereinafter referred to as "TFDA") to administer and examine food, human drugs, medical devices and cosmetics.

Article 2 The Administration shall be in charge of following matters:

1. Drafting and implementing management policies and regulations of food, human drugs, medical devices and cosmetics (hereinafter referred to as "food, drugs and cosmetics").
2. Examination and registration, review and market approval, licensing and filing for reference of food, drugs and cosmetics; supervision and review human trials of drugs.
3. Management of the production process, import testing/inspection, circulation, inspection, examination, and guidance of food, drugs and cosmetics manufacturers.
4. Analysis, research, laboratory accreditation, risk assessment and risk management of food, drugs and cosmetics, and analysis of Chinese medicines and herb.
5. Safety surveillance of food, drugs and cosmetics, and investigation and management of hazard events.
6. Inspection, reporting, alerting, and abuse prevention and education of controlled drugs. Import, export, manufacture and sale of Schedule 1 and Schedule 2 controlled drugs.
7. Promotion of consumer protection measures relating to food, drugs and cosmetics.

8. International cooperation and management prior to import of food, drugs and cosmetics.

9. Other relevant administrative matters of Food and Drug cosmetics.

- Article 3 The Administration shall have one director-general at senior grade 13; two deputy directors-general at senior grade 12. If deemed necessary, the director-general and one of the deputies directors-general in the preceding paragraph may be a medical person of Senior Grade 1 in accordance with regulations of the Medical Personnel Management Act.
- Article 4 The Administration shall have a chief secretary at senior grade 11.
- Article 5 The Administration can have research fellows and associate research fellows, who, if deemed necessary, may be appointed in accordance with the relevant regulations of the Statute Governing the Appointment of Educators. The retirement benefits and compensation for the research fellows and associate research fellows shall accord to the provisions enacted for teachers, subject to the approval of the Ministry of Health and Welfare.
- Article 6 One of director or deputy director of each division and one-fifth of the total number of senior specialists, if deemed necessary, may be a medical person of Senior Grade 1 in accordance with regulations of the Medical Personnel Management Act. The civil servant qualifications, ranks, and quota for all positions of the Administration shall be set forth separately in an organizational chart.
- Article 7 The date of implementation of the Act shall be determined by the Executive Yuan.