MEDICAL DEVICES REGULATION

Update THAILAND

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Medical Device Control Division

FDA THALAND

29 November 2010

THAILAND

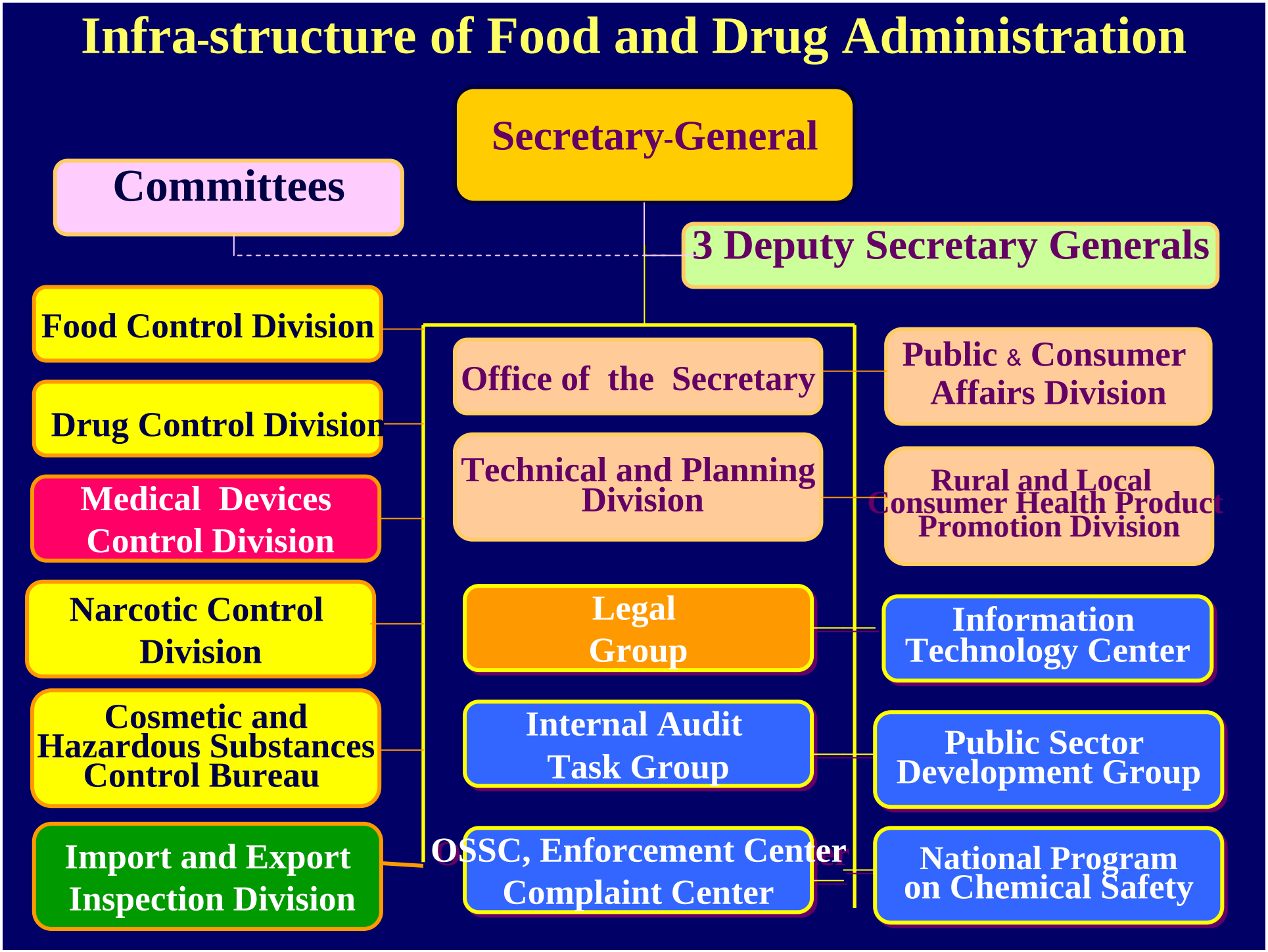
- Population 63.5 millions
- Area 513,115.02 km^2

  or 198,953 $miles^2$
- Provinces 77


สำนักงานคณะกรรมการอาหารและยา
Food and Drug Administration

Thai FDA

Infra-structure of Food and Drug Administration



VISION

" Excellent organization to protect public health and promote the use of health products which are safe, cost-effective and in good quality, leading to healthy society."

VALUE

“PROTECT”

- P (People Centric)
- R (Reliability)
- O (Ongoing Learning)
- T (Team work)
- E (Ethic)
- C (Competency)
- T (Transparency)

Mission

1) Regulate, monitor and promote for the availability of safe and good quality health products.

2) Promote the consumer knowledge and understanding in the use of safe and cost-effective health products for good health.

3) Development of management, technical skill and human resource for the excellence in health product protection.

THAI FDA - Roles and Responsibilities (1)

To protect consumer health, especially, to ensure safety, quality and efficacy of health products:

- food, drugs, psychotropic substances, narcotics, volatile substances
- medical devices,
- cosmetics and hazardous substances

THAI – FDA Roles and Responsibilities (2)

Five main areas:

1. Pre-marketing control
2. Post-marketing control
3. Surveillance program for consumers' safety
4. Consumer Education
5. Technical Support and Cooperation with other agencies

MEDICAL DEVICE ACT IN THAILAND

- Before 1988, using Drug Act 1967
- Medical Device Act 1988 (24 May 1988)
- Medical Device Control Division, Food and Drug Administration was officially established in June 1990 as regulatory authority to control manufacturing, importing, selling and advertising medical devices in Thailand.
- Medical Device Act 2008, 6 March 2008 (replaced Medical Device Act 1988)

Look at Medical Device Act 1988

Lessons learned from 20 years experience

We need to replace Medical Device Act 1988 with the New Act that:

- **increases CONSUMER PROTECTION**
- **gives more FLEXIBILITY**
- **keeps up with the CHANGE**

LAW AND REGULATION UNDER MEDICAL DEVICE ACT 2008

- Act of 129 Sections under 12 Chapters
- Ministerial Regulations
- Ministerial Notifications
- FDA rules
- MOPH rules

Addition Rules highlighted from Medical Device Act 2008 (1)

- **Establishment Licensing for manufacturing or importing of medical devices**
- **Patient Registration for announced products**
- **Technology assessment for announced products**
- **Product Liability**

Addition Rules highlighted from Medical Device Act 2008 (2)

- **Enforcement for GMP (Good Manufacturing Practice), GIP (Good Importing Practice), GDP or GSP (Good Distribution Practice or Good Selling Practice), GCP (Good Clinical Practice) Requirements**

Addition Rules highlighted from Medical Device Act 2008 (3)

- **Enforcement for Adverse Event and Device Defect Report Requirements**
- **Enforcement for Production, Import or Selling Record and Report Requirements**
- **Import and Export Control at FDA Port**

Addition Rules highlighted from Medical Device Act 2008 (4)

- **Authority to establish Device Product Standard Requirement for all classes of devices**
- **Authority to require rules, methods and conditions of manufacturing, importing and selling some medical devices**
- **Stricter control on advertising medical devices**

Addition Rules highlighted from Medical Device Act 2008 (5)

- **Authority to list medical devices selling with health professional prescription only**
- **Authority to list medical devices selling to hospital or health professional only**
- **Authority to list medical devices prohibited for direct sale or direct market**

Addition Rules highlighted from Medical Device Act 2008 (7)

- **Facilitate reclassification of medical devices based on risk factor and GHTF guideline**
- **Strengthen Interim Measures and Post-marketing Activities**
- **Increase Penalties**

REMARKS: DEFINITION OF MEDICAL DEVICES

- include Medical Devices

  For Animal Use

- include IVD products

- include Software, Spare Part and Accessories

CONTROL OF MEDICAL DEVICES

- Premarketing approval
- **Control at port by FDA inspectors with close relation with custom officers**
- **Postmarketing surveillance and vigilance**
- **Advertisement control**
- **Communication of risk information to the public**

Premarketing premise approval

1. Establishment Registration:

- ***Manufacturing Registration***

- ***Importing Registration***

2. Selling License for some medical devices

Premarketing product approval

Medical Devices are classified into 3 groups:

- ***Licensed Medical Devices***
- ***Notified Medical Devices***
- ***General Medical Devices***

Licensed Medical Devices

- ***Condoms***
- ***Surgical Gloves***
- ***Examination Gloves***
- ~~***Disposable Syringes***~~
- ~~***Insulin disposable Syringes***~~
- ***HIV test kit for diagnosis***
- ***Contact Lens***

Notified Medical Devices

- *Physical therapy devices*
- *Alcohol detectors*
- *Silicone Breast implants*
- *Breast Enhancer external use devices*
- *HIV test kits for research use*

General Medical Devices

- *Devices not on the list of Licensed medical device and Notified medical device*
- *Majorities are general medical devices*

Control of Advertisement

- **all classes of medical devices**
- any means of medical device advertisement for trading purpose must be approved before advertisement
- False or exaggerated **advertisement with any means** are prohibited

Post-Marketing Control of Medical Devices

- **premise regular inspection**
- ***product sampling check, recalling system***
- ***cease production, importation and distribution***
- ***AE reporting and vigilance system***
- ***law enforcement, public education and awareness***

Network of Control

- Provincial FDA operated by provincial health office
- Inspection at FDA port situated among all region
- Network of Expertise, Lab/Test Agency, Standard organization, Consumer Police, etc

One Stop Service Center in Thai FDA

- Pre-marketing service for all FDA responsible health products: medical device, drug,food, cosmetic, harzadous substances
- Pre-advertisement approval
- Issuing Certificates, etc

One Stop Complaint Center in Thai FDA and Adhoc Postmarketing Team

- Complaint Center for all FDA responsible health products: medical device, drug,food, cosmetic, harzadous substances
- Post-marketing service
- Post-advertisement control/monitoring
- Law enforcement

New Regulations update

- Regulations under Medical Device Act 2008
- Regulations to handle social health concerns
- Regulations to increase health protection and keep up with international standards and practices

List of Regulations	Date of Issues
1. Ministerial Regulation on Manufacturing Establishment License	19 November 2009
2. Ministerial Regulation on Importing Establishment License	19 November 2009
3. Ministerial Notification on Fees	16 October 2009

List of Regulations	Date of Issues
4. Ministerial Notification on Sign Showing Place of Manufacturing, Importing, Selling or Storaging of Medical Devices	6 March 2009
5. Ministerial Notification on Prohibited Diseases of Applicants who wish to manufacture, import or sell medical devices	30 September 2009

List of Regulations	Date of Issues
6. Ministerial Notification on Placement of Manufacturing Medical devices	28 July 2009
7. Ministerial Notification on Placement of Importing Medical devices	24 July 2009
8. Ministerial Notification on Import and Export Control Port for Medical Devices	6 March 2009

List of Regulations	Date of Issues
9. Ministerial Notification on Competent Official Identification Card	27 May 2009
10. Medical Device Committee Notification on Manufacturing Medical Devices for export purpose	14 December 2009
11. FDA Notification on Application and Approval of Advertisement of Medical Devices	November 2010

List of Regulations	Date of Issues
12. FDA Notification on Application and Approval of Manufacturing Establishment Licenses	2010
13. FDA Notification on Application and Approval of Importing Establishment Licenses	2010
14. FDA Notification on Informing Business Dissolution, Quantities and Places of Storage of Remained Medical Devices	2010

List of Regulations	Date of Issues
15. Ministerial Notification on Contact Lens	20 March 2009

Regulations on going to be released or finalized (1)

- Requirement for recording and reporting on manufacturing/importing/selling medical devices
- Requirement for reporting medical device defect and adverse events
- Labeling requirement

Regulations on going to be released or finalized (2)

- Reclassification and Control
- Standard of face mask
- Ministerial Regulations and FDA Notification on Product License Registration
- Ministerial Regulations and FDA Notification on Product Notification
- Ministerial Regulation and FDA Notification on Selling License
- E-LOGISTIC

Regulations to be done

- Enforcement of GMP
- Enforcement of GIP
- Enforcement of GDP
- Enforcement of GCP
- Technology Assessment
- Evaluation fee