ビジネス短信添付資料１（タイFDAより入手）

FOOD AND DRUG ADMINISTRATION

Guidelines for importing or ordering health products into the Kingdom of Thailand

(GIP Plus guidelines)

Good Importing Practices

conceptual framework

Pain Points

- Goods get stuck at FDA inspection checkpoint caused by incomplete or incorrect documents submitted.
- Releasing goods from FDA inspection checkpoint requires a lot of procedures and documents, which the importers need to study a lot of guidelines and may not be comfortable for entrepreneurs in order to do business.
- Good entrepreneurs as importers that follow FDA rules and regulations are facing the same problems as those that do not follow FDA rules and regulations. This may cause good entrepreneurs lack of motivation to upgrade themselves to keep them as high quality in performance of importing goods following FDA rules and regulations.
- Illegal imported health products have also been found in the market.

Motivation factor

- The economy began to recover
- Increasing in amount and value of the importation of health products under supervision of Thai FDA.

The criteria of GIP Plus are as follows:

1. Pay attention to the safety of consumers.
2. Promote importers that follow FDA rules and regulations.
3. Add benefits to motivate importers to develop and elevate themselves to keep themselves as good importers that follow FDA rules and regulations.
4. Coordinate with both internal and external departments as networks to share information regarding importation and surveillance.

The GIP Plus guidelines were developed from the Announcement of the Food and Drug Administration on Good Procedures for Importing or Ordering Health Products into the Kingdom of Thailand B.E. 2560, together with Principles of business governance. If GIP Plus guideline is implemented, it will help raise the number of good importers that follow FDA rules and regulations that are certified as importers that pass GIP Plus criteria. This will affect the safety of imported health products that import into the Thai Kingdom. Therefore, it is appropriate to give special benefits to help motivate importers to develop and elevate themselves to keep themselves as good importers that follow FDA rules and regulations, for example, in the case of imported food products, goods will be automatically released from FDA inspection checkpoint (as green line LPI). In the case of other imported health products, there will be less inspection process, less documents required, etc., this will raise the speed of doing business. Importers also receive honors to build morale and help promote the good image of importers, thus consumers will gain confidence towards importers who receive GIP Plus certification.

GIP Plus is standard for good entrepreneurs as an importer to raise the speed of doing business

Service improvement to serve the motivation factor of grouping importers (Grading).
By applying the GIP Plus guidelines, importers will be categorized into 3 groups which will be supervised by using risk-based management principles.

- Good importers will be certified as importers that pass GIP Plus criteria --> receive special benefits.
- Importers that will not be certified as importers that pass GIP Plus criteria --> undergo normal process of inspection.
- High-risk importers are importers with a history of prosecution. --> undergo a strict process of inspection.

The content of GIP Plus guidelines are as follows:

1. The GIP Plus certified health products are drugs, food, medical devices, cosmetics, hazardous substances used in households. and herbal products.
2. The qualifications of the applicant to apply for GIP Plus certificate are to have received importation license for at least 1 year and have no history of prosecution (1 year time frame)
3. Importers who pass the criteria of GIP Plus will receive a certificate + special benefits from GIP Plus. The GIP Plus certificate is valid for 3 years, there will be an audit system during these 3 years to ensure GIP Plus compliance.
4. Sanction is set up regarding the importer undergoing prosecution or fails to comply with GIP Plus criteria, such as suspension of certification for 150 days or withdrawal of certification. This will stop all benefits and privileges from the FDA.
5. The GIP Plus guidelines consist of 7 categories:
   - Chapter 1 General Requirements
   - Chapter 2 Corporation and Products
   - Chapter 3 Premises
   - Chapter 4 Tools and Equipment, Hygiene and Pest Control
   - Chapter 5 Staff
   - Chapter 6 Transport and Storage
   - Chapter 7 Handling of complaints and Recall process

Benefits and conditions for importers who is holding GIP Plus certificate

Health products of all types will receive 1) GIP Plus Certificate 2) Special advice 3) Receive honors to build morale and help promote the good image of importers 4) Receive fast track in the e-Q system

Received special facilitation for inspection at the FDA inspection checkpoint, including

Imported food products Green line privileges (automatic goods release system)

Conditions: 1) Importers must link information of certificates to all imported food products.
2) In case of random inspection (Without prior notice), the documents, products and labels, as well as collecting samples for analysis will be done at the GIP lane.

Other imported health products

1) Provide a GIP lane at FDA inspection checkpoint to promote the faster speed of all the procedures.
2) Reduce or exempt the opening of cabinets for inspection, for cosmetic products, hazardous substances used in the house, medical devices and herbal products.

Conditions : In case of random inspection (Without prior notice), the documents, products and labels, as well as collecting samples for analysis will be done at the GIP lane.

A GIP Plus certified importer can announce the GIP Plus certificate through any platform of social media (provided the year of accreditation).

ビジネス短信添付資料２（タイFDAより入手）

FOOD AND DRUG ADMINISTRATION

Documents or certificates regarding standard of food manufacturing system, Uploading and approving production system certificates via electronic system.

1. Notification of the Ministry of Public Health (No. 420) Title: Food Production Processes, Processing Equipment/Utensils and Storage Practices. Importers of the foods for sale shall hold certifying documents showing that their standards of manufacturing practices are equivalent to or not lower than the requirements prescribed in the Annex of this Notification.

2. Announcement of the Food and Drug Administration on documents or certificates regarding standard of food manufacturing system for importing food products, with the following essence:

2.1 The certificate issuing agency must be one of the following agencies:

1) the competent authorities of producer's country; or
2) other organisations that are recognised by the competent authorities of producer's country; or
3) the Certification Bodies (CB) accredited by the Accreditation Bodies (AB) that are being a member of and recognised by the International Accreditation Forum (IAF);

2.2 Details stated in the certificate include:

1) Name and Address of Manufacturer
2) Production System Standards/Regulations such as GMP, HACCP, IFS, ISO 22000, BRC, SQF etc.
3) Type of Imported food such as Beverage, Yellowtail fillet etc.
4) Scope of certification such as manufacturing, processing, chilled, frozen etc.
5) Agency that issues documents /certificates
6) Validity Period of Certificate (in case that expire date is not specified on the certificate, certificate shall be valid for no more than one year from the date of issuance or the effective date of certification)

2.3 Certificate must have at least one of the following characteristics:

1) Original document or
2) Copy of document certified by the following agencies
   2.1 Agency that issuing the certificate or
   2.2 The embassy or consulate of the producing country in Thailand or
   2.3 Government agencies in the producing country or persons certified by the state such as Notary public / Chamber of commerce / Commissioner of Oaths / Justice of Peace
3) In the case of electronic certificate or a certificate signed with an electronic signature, must be operated in accordance with the Electronic Transactions Act

2.4 Example of certificates

1. Name and Address of Manufacturer
2. Production System Standards/Regulations
3. Types of imported food and Certified activities
4. Validity Period of Certificate
5. Certification Bodies (CB)
6. Accreditation Bodies (AB)

Example of Certificates | Recognised authorities | Q&A

3. Uploading and approving production system certificates via electronic system

Inspection of imported food for sale at FDA inspection checkpoint, importers must show legal certificates to officials to release goods from FDA inspection checkpoint. In order to facilitate the ease of doing business, the Import and Export Inspection Division announced to promote the importers to upload production system certificates via electronic system. Therefore, importers no longer have to show the original certificate document at the FDA inspection checkpoint. This will promote ease of doing business and increase business opportunities for entrepreneurs.