MEMORANDUM OF UNDERSTANDING
BETWEEN
THE MINISTRY OF FOOD AND DRUG SAFETY
OF THE REPUBLIC OF KOREA
AND
THE MINISTRY OF HEALTH
OF THE SOCIALIST REPUBLIC OF VIET NAM
FOR COOPERATION ON THE SAFETY OF FOOD, PHARMACEUTICALS, COSMETICS AND MEDICAL DEVICES

The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea and the Ministry of Health (MOH) of the Socialist Republic of Viet Nam (hereinafter referred to as "the Sides"),

Desiring to cooperate in the regulatory affairs, approval, standards, specifications, import and export, and safety of food, pharmaceuticals, cosmetics, and medical devices (hereinafter referred to as "subject of cooperation"), based on the principles of equality, reciprocity and mutual benefit,

Have reached the following understanding:

Paragraph 1: Basic Principles

The Sides hereby confirm their intention to promote cooperation in accordance with Memorandum of Understanding and the relevant laws and regulations of each country.

Paragraph 2: Scope of Cooperation

This Memorandum of Understanding will apply to the following areas controlled by the Sides, including:

1. Food, including:
   (a) information exchange of laws, regulations and standards regarding food safety and quality standards;

(b) safety requirements and technical regulations of processed food (including agricultural, forest, meat, milk and fishery products under the control of the Sides);
(c) safety, standards and specifications of supplemented food, health supplement, medical food and food for special dietary uses, food additives and processing aids, food utensils, containers, packages and food contact material;
(d) food safety management, including inspection, post-marketing surveillance and laboratory testing;
(e) food safety communication; and
(f) active provision of information of the other party's relevant systems such as recognized inspection agencies and registration procedures for imported and exported food (including types of Certificate of Health, Certificate of Free Saleand Certificate of Analysis).

2. Pharmaceuticals, including:
   (a) pharmaceuticals registration regulations;
   (b) pharmaceuticals quality management(including GMP, quality testing, pre-and post-approval inspection, BA/BE, counterfeit/substandard products, drug recall, etc.);
   (c) pharmaceuticals safety management policy; and
   (d) Regulatory science and research in the field of pharmaceutical and bio-pharmaceuticals.

3. Cosmetics, including:
   (a) cosmetics management policy and regulations;
   (b) cosmetics safety surveillance; and
   (c) cosmetics quality management (including GMP, post marketingsurveillance, counterfeit cosmetic combat, etc.).

4. Medical devices, including:
   (a) medical devices safety management policy and research;
   (b) administrative procedures for obtaining commercial approval of medical devices;
   (c) post-marketing vigilance; and
   (d) evaluation of medical device manufacturing and quality control.

5. Any other areas of cooperation that may be jointly decided upon by the Sides.

Paragraph 3: Forms of Cooperation

Cooperative activities accepted by the Sides under this Memorandum of Understanding,

may include, but not be limited to:

1. Exchange of Information:
   (a) information on the relevant regime, laws, regulations and standards, regulatory approval, technology and other relevant policy of the subject of cooperation;
   (b) information on counterfeit or substandard pharmaceuticals, food products, medical devices and cosmetics; adverse reaction of pharmaceuticals, drug resistance situation, and medical devices or products recall situation and deficits;
   (c) prompt notification to the exporting Side of the safety problems detected in imported food products, investigation andcorrective measures by the exporting Side upon the receipt of the notification, and notification the importing Side of the results, including the name of the product, the risk detected, the name and address of the exporter, importer and manufacturer and relevant information; and
   (d) strengthening cooperation in information exchange and international harmonization activities of the subject of cooperation.

2. Active utilization of "Officially Authorized Inspection Agencies in Foreign Countries", the "Prior Inspection Completion System" and "Pre-confirmation based Registration System" to secure safety of food imports and vitalize food trade by preemptively indentifying any food safety hazards in producing facilities. Where either Side designates Officially Authorized Inspection Agencies in the other country, the designating Side will provide the other Side with a list of such agencies;

3. Cooperation to expedite onsite inspection of exporters' facilities on food;

4. Holding joint symposiums, workshops, conferences and/or offering joint training courses, subject to the availability of the resources and funds of each Side; and

5. Any other areas of cooperation that may be jointly decided upon by the Sides.

Paragraph 4: Operation of High-level Consultation

1. The Sides will establish the Consultation between High-level Officials (hereinafter referred to as "the High-level Consultation") to promote and discuss cooperative activities under this MOU.

2. The High-level Consultation will be headed by the Minister of the Ministry of Food and Drug Safety of the Republic of Korea and the Minister of the Ministry of Health of the Socialist Republic of Viet Nam, or the representatives designated respectively by the Ministers of the Sides.

3. The meeting of the High-level Consultation will be held biennially and alternately in Korea and Viet Nam, unless otherwise decided by the Sides.

4. The Working-level Consultation of each area as laid down in Paragraph 5 may be established to support the activities of the High-level Consultation and to achieve substantive cooperation in each area. The Working-level Consultation will be in operation in accordance with the High-level Consultation.

5. The composition and agenda for the meeting of the High-level Consultation will be decided upon by the Sides in advance.

6. The Sides will designate their respective contact points to ensure efficient operation of the High-level Consultation.

Paragraph 5: Operation of Working-level Consultation

1. Pursuant to Paragraph 4, the Working-level Consultation will be divided into specialized areas such as food safety and pharmaceuticals and will assist the High-level Consultation.

2. In principle, the Meetings of Working-level Consultation will be held annually and alternately in Korea and Viet Nam, unless otherwise jointly decided upon by the both Sides. The Working-level Consultation in the area of Food Safety will involve food standard experts from the Vietnam Food Administration (VFA) and MFDS in order to include discussions related to food standard in the Consultation.

3. Heads of the Working-level Consultation will be respective officials at the Director-General level from the Sides.

4. Where deemed necessary for its operation, the Working-level Consultation may involve private experts or stakeholders of the industry with the consent of the Sides.

5. The composition and agenda of meetings for each area of the Working-level Consultation will be decided upon by the Sides in advance.

6. The Sides will designate their respective contact points to ensure efficient operation of the Working-level Consultation.

Paragraph 6: Contact Points

The Sides hereby designate the following points in order to ensure the efficient implementation of this Memorandum of Understanding:

a) for the "MFDS": International Cooperation Office

b) for the "MOH": International Cooperation Department

Paragraph 7: Financial Arrangements

1. Each Side will bear its own costs in relation to cooperative activities under this Memorandum of Understanding.

2. Cost of any assistance provided by either Side at the request of the other will be borne by the requesting Side, unless otherwise decided by the Sides.

Paragraph 8: Release of Information

Neither Side may disclose or distribute to any third party any confidential information transmitted by the other Side in the process of cooperative activities under this Memorandum of Understanding, except as and to the extent authorized in writing to do so by that other Side.

Paragraph 9: Resolution of Disputes

Any disputes arising from the interpretation and/or implementation of this Memorandum of Understanding will be resolved amicably through consultations between the Sides.

Paragraph 10: Validity, Amendment and Termination

1. This Memorandum of Understanding of Cooperation will come into effect on the date of its signature and will remain effective for a period of five years. It will be automatically renewed for successive periods of five years, unless either Side notifies the other in writing of its intention to terminate this Memorandum of Understanding six months in advance.

2. This Memorandum of Understanding may be amended with the mutual written consent of the Sides.

3. The termination of this Memorandum of Understanding will not affect the duration or validity of any cooperative activities under this Memorandum of Understanding, which are in progress at the time of the notification of the termination of this Memorandum of Understanding.

4. Upon its entry into effect, this MOU will terminate and replace the Memorandum of Understanding between the Ministry of Food and Drug Safety of the Republic of Korea and the Ministry of Health of the Socialist Republic of Viet Nam for Cooperation on the Safety of Food, Drug, Cosmetic and Medical Device, that was signed in Osong Korea, on 2 December 2015.

Signed in duplicate in Ha Noi, Viet Nam, on 16 May 2018, in two copies in English language, both texts being equally authentic.

For the Ministry of Food and Drug Safety of the Republic of Korea	**For the Ministry of Health of the Socialist Republic of Viet Nam**
RYU, Youngjin	**Nguyen Thi Kim Tien**
Minister	**Minister**