# MEMORANDUM OF UNDERSTANDING BETWEEN THE MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF KOREA

#### AND

# THE CHINA FOOD AND DRUG ADMINISTRATION OF THE PEOPLE'S REPUBLIC OF CHINA FOR COOPERATION ON THE SAFETY OF FOODS, DRUGS, COSMETICS AND MEDICAL DEVICES

The Ministry of Food and Drug Safety of the Republic of Korea and the China Food and Drug Administration of the People's Republic of China(hereinafter referred to as "the Sides"),

Recognizing mutual benefits of protecting the public health of the Sides through enhancing cooperation for information and sharing experience with respect to regulation and safety of foods (including health foods), drugs, cosmetics and medical devices (hereinafter referred to as "the subject of cooperation") on the basis of equality, reciprocity and mutual benefit, and

Hoping to work together for information on regulation, approval, standards, import and export, and safety of the subject of cooperation,

Have reached the following understanding:

#### Paragraph 1 Basic Principles

The Sides will:

- 1. endeavor to exchange information on regulation, approval, standards, import and export, and safety of the subject of cooperation;
- 2. expand a concrete partnership in carrying out cooperative activities provided for in Paragraph 2 based on the principles of mutual interest and respect; and
- 3. discuss opinions on a regular basis concerning areas in need of cooperation between the Sides through exchange of personnel and meetings.

## Paragraph 2 Areas of Cooperation

The Sides will cooperate in the following activities:

- 1. Exchange of information regarding regime, legislation, regulatory approval and other relevant policy of the subject of cooperation;
- 2. Mutual exchange of information on safety of the subject of cooperation including imported and exported pharmaceutical products of mutual concerns. Where both Sides recognize the need for an on-site inspection to each other, the Sides will cooperate in such on-site inspection carried out for the safety problem in the subject of cooperation including pharmaceutical products;
- 3. Holding symposia and/or offering joint training courses, subject to the availability of the funds and resources of each Side; and
- 4. Promoting exchange of information on exported products, businesses and their adversity of the Sides.

### Paragraph 3 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 Minister of the Ministry of Food and Drug Safety and Minister of the China Food and Drug Administration, or representatives designated respectively by Ministers of the Sides.
- 3. The meeting of the High-level Consultation will be held annually and alternately in Korea and China, unless otherwise decided by the Sides.
- 4. The Working-level Consultation of each area as laid down in Paragraph 4 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 4 Operation of Working-level Consultation

- 1. Pursuant to Paragraph 3, the Working-level Consultation will be divided into specialized areas and assist the High-level Consultation.
- 2. The Working-level Consultation will basically consist of four areas: foods (including health foods), drugs, cosmetics and medical devices, unless otherwise decided by the High-level Consultation.
- 3. Meetings of Working-level Consultation will be held annually and alternately in Korea and China according to the decision of the High-level Consultation.
- 4. Heads of the Working-level Consultation will be respective officials at the Director-General level from the Sides.
- 5. 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.
- 6. The composition and agenda of meetings for each area of the Working-level Consultation will be decided upon by the Sides in advance.
- 7. The Sides will designate their respective contact points to ensure efficient operation of the Working-level Consultation.

#### Paragraph 5 Financial Arrangements

- 1. Each Side will bear its own costs in relation to cooperative activities under this MOU.
- 2. Costs 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 6 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 MOU, except as and to the extent authorized in writing to do so by that other Side.

#### Paragraph 7 Resolution of Disputes

Any disputes in the interpretation and/or implementation of this MOU will be resolved amicably through consultations between the Sides.

#### Paragraph 8 Validity and Termination

- 1. This MOU will come into effect on the date of its signature and will remain effective for a period of five (5) years. It will be automatically renewed for successive periods of five (5) years, unless either Side notifies the other in writing of its intention to terminate this MOU six (6) months in advance.
- 2. This MOU may be amended with the mutual written consent of the Sides.
- 3. The termination of this MOU will not affect the duration or validity of any cooperative activities under this MOU which are in progress at the time of the notification of the termination of this MOU.

Signed in duplicate in Beijing on December 19, 2013, in the Korean, Chinese and English languages, all three texts being equally authentic. In case there is any divergence of interpretation of this MOU, the English text will prevail.

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the Ministry of Food and Drug Safety of the Republic of Korea For the China Food an

the China Food and Drug Administration of the People's Republic of China