

United States of America and the Ministry of Health of the Socialist Republic of Vietnam Concerning Food, Animal, Feed, and Medical Products

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Memorandum of Understanding between the Department of Health and Human Services of the United States of America and the Ministry of Health of the Socialist Republic of Vietnam Concerning Food, Animal, Feed, and Medical Products

Between the Department of Health and Human Services of the United States of America and the Ministry of Health of the Socialist Republic of Vietnam Concerning Food, Animal, Feed, and Medical Products

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The Department of Health and Human Services ("HHS") of the United States of America ("United States") and the Ministry of Health ("MOH") of the Socialist Republic of Vietnam ("Vietnam") (hereinafter referred to as "the Participants");

Recalling the Agreement between the Government of the United States and the Government of Socialist Republic of Vietnam on Scientific and Technical Cooperation, signed in 2000; the Agree between the Government of the United States and the Government of the Socialist Republic of Vietnam on Economic and Technical Cooperation, signed in 2005; the Agreement between the Government of the United States and the Government of the Socialist Republic of Vietnam on H and Medical Sciences Cooperation, signed in 2006; and the Joint Statement of Cooperation betw the Department of Health and Human Services of the United States of America and the Ministry Health of the Socialist Republic of Vietnam of 1997;

Understanding the mutual benefits of protecting the public health through bilateral cooperation exchange between the Participants with regard to the safety of food and animal feed, and the s and effectiveness of medical products;

Appreciating the bilateral cooperation the U.S. Food and Drug Administration of HHS (HHSIFDA) enjoyed to date with agencies within MOH and the Department of Agriculture, Forestry and Fish Quality Assurance ("DAFFQA") within the Ministry of Agriculture and Rural Deve1opment ("MARI

Desiring to deepen bilateral cooperation between the Participants to protect the safety and heal humans and animals in the United States and in Vietnam, and to prevent, intervene in, and res any safety issues related to food and animal feed, and cooperation on any issues of safety and effectiveness related to medical products exported from one country to the other;

Recognizing that such cooperation can improve and promote the health of people in the United and Vietnam and enhance confidence in the safety of food and animal feed and the safety and effectiveness of medical products exported from one country to the other;

Have reached the following understanding:

Section 1 – Purpose and Principles

- A. The purpose of this Memorandum of Understanding ("MOU") is to express the Participants' intent to cooperate bilaterally regarding the safety of food and animal feed and the safety and effectiveness of medical products. This is a non-binding MOU and nothing in it is intended to create legal obligation under international or other law.
- B. The Participants expect the cooperation provided for in this MOU to promote public health and help ensure that products exported from either country are safe and meet applicable standards, including relevant U.S. standards.
- C. The Participants are to conduct all activities pursuant to this MOU in accordance with their respective laws and regulations. Each Participant is responsible for funding its own activities under this MOU, subject to the availability of personnel, resources, and appropriated funds, unless the Participants otherwise decide.

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Section 2 – Scope of Cooperation

- A. As understood by HHS/FDA in this MOU:
 1. "Medical products" includes drugs intended for use in humans or other animals, vaccines and biologics and medical devices for use in humans;
 2. "Food" includes articles used for food or drink for humans or other animals, and articles used for components of any such article; and
 3. "Animal feed" includes articles used for food or drink for animals other than humans and articles used for components of any such article.
- B. As understood by MOH and MARD in this MOU:
 1. "Medical products" includes drugs, including traditional and herbal medicine, vaccines and other biological products, cosmetics, and medical devices for use in humans;
 2. "Veterinary drugs" includes substances or compounds originating from animals, plants, microorganisms, minerals, chemicals, which are used to prevent, diagnose and treat diseases or to rehabilitate, regulate, or improve any functions of the bodies of animals, including pharmaceuticals, chemicals, vaccines, hormones, some other bio-products and a number of veterinary-use microorganisms.
 3. "Food" includes anything that contains or consists of nutrients and is regarded by people as appropriate for consumption, including food additives, food supplements, and health food.
 4. "Animal feed" includes foodstuffs grown or developed for livestock and poultry to maintain the health of animals and to increase the quality of such end products as meat, milk or eggs.
- C. Recognizing that each Participant has jurisdiction over specific products and defines those products differently, collaboration under this MOU is intended to extend only to medical products, food, and animal feed under the jurisdiction of both Participants and subject to regulatory systems that permit meaningful collaboration between them.

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Section 3 – Information Sharing

The Participants intend to exchange the following:

1. Information on their respective regulatory systems;
2. The text of laws and regulations relevant to their respective regulatory systems;
3. Guidance documents or other relevant information concerning their respective regulatory systems for food, animal feed, and medical products;
4. Updated information on drugs approved by HHS/FDA for use in aquaculture;
5. Information concerning training opportunities related to food, animal feed, and medical products, including the safety of medical products after they are placed on the market (post-marketing surveillance); and
6. Relevant and timely information on potential or emerging issues of product safety with regard to imported or exported foods, food-borne illnesses, and food contamination, as decided by the Participants.

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Section 4 – Regulatory Cooperation

- A. The Participants intend to cooperate with respect to conducting or participating in workshops or other training concerning food, animal feed, and medical products, including those offered by international organizations.
- B. HHS/FDA and MARD/DAFFQA intend to continue existing collaborative efforts to lead to an exchange of letters concerning the safety of fish and fishery products exported from Vietnam to the United States.

- C. HHS/FDA and the appropriate agencies within MOH intend to cooperate on training in Good Clinical Practice and the regulatory inspection of clinical trials to support the development of medical products.
- D. HHS/FDA and MOH's Food Administration intend to investigate opportunities regarding training on risk analysis, surveillance, investigation, and inspection for food-borne illnesses and their oversight of importation and exportation.
- E. HHS/FDA and the appropriate agencies within MOH and MARD intend to cooperate on continued participation in HHS/FDA's Center for Drug Evaluation and Research Forum relating to training on the evaluation of medical products marketing authorization applications, to ensure the safety of medical products before granting marketing authorization.
- F. HHS/FDA and the appropriate agencies within MOH and MARD intend to investigate opportunities for sharing up-to-date scientific information related to risk management, standards, and Good Agricultural Practices concerning the safety of food and animal feed through training, workshops, exchanges, and other forms of cooperation.

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Section 5 – Final Provisions

This MOU is to come into operation upon signature by the Participants, and should continue for five (5) years from that date. The Participants may decide in writing to extend this MOU for additional five (5) year terms. The Participants may decide in writing to revise this MOU, and either Participant may discontinue it at any time, but should give 60 days' written notice to the other Participant. The discontinuation of this MOU is not intended to affect the validity or duration of projects initiated pursuant to this MOU prior to such discontinuation.

Signed at Washington, D.C., in duplicate, this 24th day of June 2008, in both the English and Vietnamese languages.

For The Department of Health and Human Services of the United States of America:

Tevi Troy

For The Ministry of Health of the Socialist Republic of Vietnam:

Cao Minh Quang

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