

**AGREEMENT BETWEEN
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
OF THE UNITED STATES OF AMERICA
AND
THE STATE FOOD AND DRUG ADMINISTRATION
OF THE PEOPLE'S REPUBLIC OF CHINA ON
THE SAFETY OF DRUGS AND MEDICAL DEVICES**

The Department of Health and Human Services ("HHS") of the United States of America ("United States") and the State Food and Drug Administration ("SFDA") of the People's Republic of China ("China") (hereinafter referred to together as "the Parties"):

Understanding the mutual benefits of protecting the public health through improved cooperation between the Parties with regard to monitoring and regulating the safety of drugs and medical devices;

Desiring to work together to better ensure the safety and quality of Drugs, Excipients, and Medical Devices; and

Recognizing that such cooperation can improve the health of the citizens of both the United States and China and enhance confidence in the regulation of Drugs, Excipients, and Medical Devices in both countries;

Have agreed as follows:

Article I Purpose

The purpose of this Agreement is to establish methods of cooperation between the Parties that will provide the Food and Drug Administration within HHS ("HHS/FDA") with additional information about products exported from the customs territory of China to the United States, provide SFDA with increased sharing of information about products

exported from the United States to China, and encourage further regulatory cooperation between the Parties regarding Drug and Medical Device regulation.

Article II General Principles

- A. The Parties shall engage in regulatory cooperation regarding the export of Drugs, Excipients, and Medical Devices from the customs territory of China to the United States and Drugs, Excipients, and Medical Devices produced in the United States and exported to the customs territory of China as set out in Article VI and as further defined in Work Plans to be agreed upon by the Parties.
- B. The Parties shall engage in information-sharing to improve their mutual understanding of, and to gain greater confidence in, each Party's regulatory system as set out in Article V and as further defined in Work Plans to be agreed upon by the Parties. As specified in Article V, each Party shall share relevant information with the other Party, including on relevant laws, regulations, areas of jurisdiction, and public health and safety.
- C. The Parties shall engage in regulatory cooperation regarding improving the authenticity, quality, safety, and effectiveness of Drugs, Excipients, and Medical Devices as set out in Articles IV and VI and as further defined in Work Plans to be agreed upon by the Parties.
- D. The Parties shall commit to annual meetings between senior Agency leaders to discuss and evaluate progress under this Agreement, among other things.

Article III Definitions

For purposes of this Agreement the following definitions shall apply:

- A. "API" or "Active Pharmaceutical Ingredient" means any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

- B. "Counterfeit Drugs and Medical Devices" means a product that is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to branded and generic products and may include products with correct ingredients, with wrong ingredients, without active ingredients, with incorrect quantity of active ingredient, or with fake packaging.
- C. "Designated Drugs and Designated Medical Devices" means a Drug (including APIs) and Excipients or Medical Device, respectively, designated for inclusion in each phase of implementation, based on criteria established in Article IV. A.
- D. "Drug" means any material commonly used for human pharmaceutical use. The term includes the following materials:
1. Finished-dosage forms (including both over-the-counter ("OTC") and prescription drugs);
 2. Drug substance, or active pharmaceutical ingredients ("APIs");
 3. Biologic drugs (e.g., vaccines and monoclonal antibodies); and
 4. Products taken by mouth intended to supplement the diet that:
 - (i) bear or contain one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use in humans to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any of the above; and
 - (ii) meet any one of the following characteristics:
 - are not clearly labeled as dietary supplements; or
 - contain claims to diagnose, cure, mitigate, treat, or prevent disease; or
 - contain substances that are regulated by HHS/FDA as APIs.
- E. "Excipient" means any components other than APIs that are commonly used in a pharmaceutical product. These components may include vehicles and additives, such as dyes, flavors, binders, emollients, fillers, lubricants, and preservatives.
- F. "Firm" means any business within the customs territory of China or within the United States that is engaged in the manufacture (including processing) and distribution (including export) of Drugs, Excipients, and Medical Devices.
- G. "HHS/FDA Requirements" means any U.S. laws, regulations or other requirements, including any amendment adopted after the date of entry into force of this Agreement,

concerning Drugs, Excipients, and Medical Devices that are administered or enforced by HHS/FDA.

“SFDA Requirements” means any Chinese laws, regulations or other requirements, including any amendment adopted after the date of entry into force of this Agreement, concerning Drugs, Excipients, and Medical Devices that are administered or enforced by SFDA.

- H. “Medical Device” means any instrument, apparatus, machine, implant, *in vitro* reagent, or similar or related article, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans, or intended to affect the structure or any function of the human body, and which is not a drug.
- I. “SFDA-Registered Firm” means a Firm that SFDA has determined meets SFDA Requirements and that is registered with SFDA.
“HHS/FDA-Registered Firm” means a firm that complies with U.S. registration and listing requirements and that is registered with HHS/FDA.
- J. “Facility” means any Firm’s site within the customs territory of China or in the United States that is engaged in manufacturing, producing, processing, packing, testing, holding, transporting, distributing, or exporting Drugs, Excipients, and Medical Devices.

Article IV Import/Export Tools

A. Determination of Designated Drug and Designated Medical Devices

This Article will be implemented in a phased approach, beginning with a defined list of Designated Drugs and Designated Medical Devices. The Parties shall conduct a formal evaluation of the implementation of this Article for the products designated in paragraph 2 at the conclusion of the 12-month period described in Article VII.D and annually thereafter. Based on the Parties’ determination of the success of this program, the Parties may agree to add or delete specific Drugs, Excipients, and Medical Devices. Timing for the evaluation will be established through the Work Plan.

1. *Factors.* The Parties shall consult on the designation of which products to include in each phase, as appropriate, based on the following factors:

- a. potential or actual, direct or indirect risk to the public health associated with the product, based on testing, inspection results or other relevant information;
- b. the rate of refusal of admission in either Party's country or of problems associated with the product before, during or after entering the domestic commerce of the other Party's country, including product recalls, safety alerts and enforcement actions;
- c. fraudulent or deceptive labeling or indications of any substitution or additions of a substance to a product or an ingredient of a product that reduces the quality of the ingredient or product or makes it appear of greater value than it is, without clearly revealing such substitution or addition to the recipient in the importing country;
- d. promotion or advertising of products intended for consumers of the importing country, beyond the products' approved indications for use; and
- e. the feasibility of implementing an effective and timely Work Plan with respect to the product.

2. *First Phase – Designated Drugs and Designated Medical Devices.*

The Parties agree that the first phase shall include products designated by each Party. Designated Drugs shall include any substance or chemical that may be used as an API for any Designated Drug under this Agreement, even if the entity manufacturing or distributing the substance or chemical does not identify the product as an API. Details on these designations shall be determined through the Work Plan. Designated Drugs and Designated Medical Devices shall include:

- a. SFDA-Designated Drugs:
 - i. Recombinant Human Insulin
 - ii. Lysine Fat and Lysine Salt
 - iii. Cefoperazone and its salts
 - iv. Paclitaxel injection
 - v. Penicillin and its finished dosage form
 - vi. Diagnostic kit for blood screening, specifically, for HIV/AIDS and Hepatitis B & C
- b. SFDA-Designated Medical Devices:
 - i. Intraocular Lenses

- ii. Cardiac pacemakers
- c. HHS/FDA-Designated Drugs:
 - i. Gentamicin sulfate
 - ii. Atorvastatin
 - iii. Sildenafil
 - iv. Dietary supplements intended for erectile dysfunction or sexual enhancement
 - v. Human Growth Hormone
 - vi. Oseltamivir
 - vii. Cephalosporins manufactured in facilities that also manufacture non-cephalosporin drugs
 - viii. Glycerin
- d. HHS/FDA-Designated Medical Devices:
 - i. Glucose test strips
 - ii. Condoms

B. Registration and Collaboration on Designated Drugs and Designated Medical Devices

1. With respect to Designated Drugs and Designated Medical Devices:
 - a. For those designated by HHS/FDA, SFDA shall require that all Firms that manufacture Designated Drugs and Designated Medical Devices intended for export to the United States are registered by SFDA.
 - b. For those designated by SFDA, HHS/FDA shall provide SFDA with the following available information as agreed to in the Work Plan:
 - i. the facilities that manufacture the products;
 - ii. information from the product approval or clearance package;
 - iii. recalls, warning letters, and enforcement actions; and
 - iv. reported post-marketing adverse events
2. HHS/FDA shall consult with SFDA to assist SFDA in understanding HHS/FDA Requirements for Designated Drugs and Designated Medical Devices.
3. HHS/FDA and SFDA shall review the HHS/FDA Requirements for the Designated Drugs and Designated Medical Devices and the SFDA Requirements for the Designated Drugs and Designated Medical Devices to understand the differences and identify the means to ensure the quality, safety, and authenticity

of Designated Drugs and Designated Medical Devices, given different regulatory systems.

4. SFDA shall maintain documents on file related to reviews, inspections, testing, recalls, compliance, and any other assessment of a Firm of Designated Drugs and Designated Medical Devices. SFDA shall make such records available to HHS/FDA within 7 work days of an HHS/FDA request.

C. Future Collaboration on Registration and Certification

The Parties agree to pursue activities to better understand the differences and the gaps between HHS/FDA and SFDA requirements and establish mechanisms to address those gaps. Specifically, SFDA shall actively create conditions to enable SFDA to certify that HHS/FDA Requirements are met for firms producing Designated Drugs and Designated Medical Devices intended for export to the United States. Once these new conditions mature for SFDA, the Parties may agree to modify this Agreement to include provisions that provide for the certification of products, exported from the customs territory of China to the United States, to HHS/FDA requirements, and for appropriate export control mechanisms.

D. Product Integrity and Security

1. The Parties shall cooperate on the establishment of the pedigree (chain-of-custody) systems, as follows, for those Drugs designated under Article IV A. that are identified in the Work Plan as being at risk for counterfeiting;
 - a. The Parties shall establish and implement measures, including pedigree requirements, to further ensure the integrity and security of Designated Drugs. The Parties shall collaborate with each other on the establishment of such pedigree requirements for both domestic and exported Designated Drugs.
 - b. The Parties shall establish and implement pedigree systems. The pedigree shall include information on Designated Drugs and their manufacturers as follows:
 - i. product information (drug name, manufacturer, product registration or identification number);
 - ii. item information (unique product serial number, dosage form, strength, container size, lot number, expiration date);

- iii. information about each party to the transaction (including company name, street address, license number, contact person, and telephone number); and
 - iv. transaction information (date product was shipped from seller, date received by purchaser).
- c. Each Party shall establish and implement standards for a comprehensive electronic tracking system for each unique package.
2. The Parties shall also work on the following product integrity and security measures for all Drugs:
- a. Each Party shall enhance enforcement against entities that fail to provide a pedigree, provide a false pedigree, or fail to comply with any other provisions related to the integrity or security of Drugs.
 - b. Each Party shall develop a program to inform and educate supply-chain stakeholders and the public on how to avoid and minimize their risk of receiving a misbranded, adulterated or Counterfeit Drug or Medical Device, and how to report suspect drugs, excipients, medical devices and suspicious parties.
 - c. SFDA and HHS/FDA shall respond rapidly to, and investigate reports of, Drugs, Excipients, and Medical Devices suspected of being misbranded, adulterated, or counterfeited. SFDA and HHS/FDA shall also notify each other of any such reports and the steps they have taken or plan to take to investigate the report. SFDA and HHS/FDA shall also report Counterfeit Drugs to the World Health Organization (WHO).
 - d. Each Party shall take steps to adopt and implement regulations and practices (e.g., good distribution practices) and guidelines (e.g., pharmacovigilance, rapid response for counterfeits) consistent with those established by the World Health Organization (WHO) including with respect to Counterfeit Drug identification and prevention, including the enforcement of laws and regulations that encompass APIs, Excipients, and finished-dosage forms misidentified as to source and composition. Details of the collaboration on standards shall be determined through the Work Plan.
 - e. Each Party shall endeavor to enhance cooperative activities with its appropriate law-enforcement and regulatory authorities to actively

investigate and prosecute individuals or entities that manufacture, sell, distribute, handle, test, trade, or export misbranded, adulterated, or Counterfeit Drugs, Excipients, and Medical Devices. Each Party shall actively participate in the WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT), and the Permanent Forum on International Pharmaceutical Crime (PFIPC).

Article V Information Sharing

The Parties shall exchange information related to Drugs, Excipients, and Medical Devices and their respective regulatory systems concerning Drugs, Excipients, and Medical Devices, on a timeframe and with updates as agreed to in the Work Plan, as follows:

- A. A Party may provide information to the other Party in the English or Chinese language.
- B. The Parties shall exchange copies of and other relevant information concerning their respective laws and regulations.
- C. HHS/FDA and SFDA shall provide each other with copies of all relevant HHS/FDA and SFDA Requirements, updated as appropriate, with respect to Designated Products.
- D. Each Party shall provide to the other Party a list of all registered API manufacturers, and the products they manufacture, in its respective country.
- E. Each Party shall notify the other Party of serious adverse health consequences or death relating to product safety, manufacturing conditions, recalls, serious adverse event reports, and other instances or the gross deception of consumers. Each Party shall promptly respond to requests from the other Party for information concerning any such risk, including contact information for the Firms or other entities concerned. The Work Plan shall include specific commitments to ensure the timeliness of any such notification or response.
- F. HHS/FDA shall work with SFDA to better understand the Global Harmonization Task Force (GHTF) National Competent Authority Reporting (NCAR) program, to support both Parties' actively reporting any serious adverse events that involve medical devices into the NCAR program.

- G. Each Party shall notify the other Party of its determination that a shipment of Drugs, Excipients, or Medical Devices has been shipped to the other Party's country, for which there is a reasonable probability that the use of, or exposure to, the product will cause serious adverse health consequences or death. The notification shall:
1. Be in writing;
 2. Be made within 24 hours of the determination;
 3. Include the reasons for the determination; and
 4. Include, as it becomes available, other information that may assist the other Party to identify the shipment and the supplier.
- H. Within 30 calendar days of entry into force of this Agreement, each Party shall provide the other with a list of Firms that manufacture Drugs and Medical Devices in its country and are registered in its country, and the products each Firm manufactures. SFDA shall provide to HHS/FDA the list of Drug, Excipients, and Medical Device manufacturers in the customs territory of China that SFDA has determined to be out of compliance with SFDA Requirements, when such a list becomes available.
- I. Within 30 calendar days of a request from HHS/FDA, SFDA shall provide HHS/FDA inspection reports requested by HHS/FDA for SFDA-Registered Firms that manufacture or distribute Drugs, Excipients, or Medical Devices that have been or will be exported to the United States. SFDA shall notify HHS/FDA within 10 calendar days of becoming aware of inspection results that indicate significant deficiencies or fraud associated with firms that manufacture or distribute Drugs, Excipients, or Medical Devices that SFDA determines have been or will be exported to the United States. Once HHS/FDA has addressed any remaining remote access issues, HHS/FDA will grant SFDA access to an electronic database of HHS/FDA inspection results.
- J. Each Party shall notify the other Party of any Counterfeit Drug, Excipient, or Medical Device found in its country, including information about the source and distribution.

Article VI Regulatory Cooperation

The Parties shall accomplish the following tasks, as it relates to Drugs, Excipients, and Medical Devices:

- A. Develop and set out in the Work Plan specific steps and measures to prevent and control Counterfeit Drugs, Excipients and Medical Devices.
- B. Develop appropriate regulatory cooperative activities, including training programs and scientific discussions or cooperation, intended to support the long-term stability and effectiveness of the registration and certification programs. For each training or other cooperative activity that requires travel or other organizational costs, each Party shall bear the cost for its respective participants. Appropriate regulatory cooperative activities may include:
 - 1. development and coordination of the training programs for Chinese inspectors;
 - 2. technical exchanges and training relating to the use of Good Clinical Practice (GCP)s to ensure the safety of human subjects and the collection of valid clinical data; and
 - 3. training and exchange on the development of evaluation review methods, inspection techniques, establishment of computer databases, evaluation report standard formats, and the development of technical guidance documents, and laws and regulations.
- C. The Parties shall cooperate on the implementation of standards.
 - 1. The Parties shall develop through the Work Plan details of collaboration on the establishment of internationally-recognized standards. These standards may include:
 - a. the International Pharmaceutical Excipients Council's standards for excipients;
 - b. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines, including ICH Q7A Current Good Manufacturing Practice Guideline for APIs;
 - c. Pharmaceutical Inspection Cooperation Scheme (PIC/S) GMP Standards for Finished-Dosage Form Pharmaceuticals; and
 - d. Global Harmonization Task Force Standards, including ISO 13485 medical device requirements.
 - 2. Upon request, HHS/FDA shall provide assistance to SFDA regarding internationally-recognized standards.
- D. Each Party shall develop a streamlined process for facilitating (e.g., issuing a letter of invitation) an inspection by a Party in the other Party's country no later than 5 calendar days after receipt of such a request from a Party. Such inspection may be

conducted with or without providing advance notice (as specified in the request) to the establishment concerned. The performance measure for this activity shall be the number of days that elapse between the Party's request and the other Party's response in facilitating the inspection.

- E. Each Party may request the other Party to conduct an investigation regarding any Drug, Excipient, or Medical Device, exported from the other Party's country to the Party's country, that the Party has reason to believe may pose a risk to public health or safety. The Party shall respond to the requesting Party within 3 calendar days of the receipt of the request, informing the requesting Party of its decision on whether or not to conduct an investigation. If the decision is to conduct an investigation, the Party shall notify the requesting Party within 15 calendar days from the decision to conduct the investigation of:
1. information relating to the source of the health or safety risk;
 2. steps taken to remedy the risk; and
 3. the outcome of any remediation.

The Work Plan shall set out requirements and performance measures related to investigations under this paragraph.

- F. HHS/FDA may fully participate in any annual or other SFDA inspection of any SFDA- or HHS/FDA- Registered Firm in the customs territory in China exporting to the United States.
- G. Except in extraordinary circumstances, each Party will observe the following procedures: each Party shall publish on its website(s) all proposed regulations and other measures related to Designated Drugs and Designated Medical Devices and allow a reasonable period of time for all interested parties to submit comments. Each Party shall consider such comments and, at the time final regulations are adopted, address in writing significant, substantive comments received from interested persons during the comment period and explain any substantive revision made to the proposed regulations. Both Parties shall also publish on its website all final regulations and measures related to Designated Drugs and Designated Medical Devices and allow a reasonable amount of time before implementation and enforcement. Both Parties shall also publish all of the information listed above in the relevant government publication (i.e., HHS/FDA, the *Federal Register*). Pending the designation of a

single relevant government publication for this purpose in China, SFDA shall ensure its website is kept current, so as to assure transparency in rulemaking.

- H. HHS/FDA shall report any science and technology cooperation to the Joint Commission on Scientific and Technological cooperation established under the Agreement between the Government of the United States of America and the Government of the People's Republic of China on Cooperation in Science and Technology, signed at Washington January 31, 1979.

Article VII Administration

- A. Within 15 calendar days of the date of entry into force of this Agreement, each Party shall notify the other Party in writing of its primary points of contact for coordinating all bilateral activities under this Agreement, including coordinating meetings, exchanging information, and sending and receiving notifications.
- B. The Parties hereby establish a Working Group. Within 30 calendar days of the date of entry into force of this Agreement, each Party shall identify relevant policy and technical experts of each Party to serve on the Working Group.
- C. Within 60 calendar days of the date of entry into force of this Agreement, the Working Group shall hold its first meeting to develop a Work Plan that:
1. further details specific activities each Party shall perform pursuant to this Agreement within the first 12-month period following the date of entry into force of this Agreement and time lines for the completion of each such activity; and
 2. includes, as appropriate, performance measures to evaluate the success of each such activity.
- D. Within 120 calendar days of the date of entry into force of this Agreement, the Working Group shall finalize the Work Plan for the first 12-month period following the date of entry into force of this Agreement. The Parties shall assess the Work Plan at the conclusion of the 12-month period.
- E. For each subsequent 12-month period, the Working Group shall meet to develop a Work Plan that further details specific activities that each Party shall perform pursuant to this Agreement within that period and, as appropriate, that includes performance measures to evaluate the success of each such activity. The Parties shall assess each such Work Plan at the conclusion of the relevant period.

- F. The Work Plan for each 12-month period, when adopted by the Parties, shall include binding commitments for the effective and timely implementation of this Agreement. Each Party shall make the Work Plan for the first 12 months, and each subsequent year, publicly available on its respective website.
- G. Within 180 calendar days of the date of entry into force of this Agreement, high-level representatives of the Parties shall meet to discuss and review the implementation of and progress under this Agreement and related matters.
- H. Thereafter, the high-level representatives of the Parties shall meet on an annual basis to discuss and review the implementation of and progress under this Agreement and related matters. Unless the Parties otherwise agree, the location of these annual meetings shall alternate between the United States and China. The Parties may convene additional technical or program-level meetings on an as-needed basis in any mutually agreeable location.
- I. For each provision in this Article, each Party shall notify the other Party within 24 hours of determining it will be unable to meet an agreed-upon deadline, for such reasons as U.S. or Chinese holidays, or for any other reason, and will provide the reason for the delay. The Parties may then agree to modify the timelines and establish a new delivery date. Such notification shall occur through the designated points of contact established as per Article VII. 1.

Article VIII Performance Measures

- A. The Parties shall evaluate and discuss progress under this Agreement on an annual basis, including the effectiveness of SFDA's registration program established pursuant to the Work Plan. HHS/FDA may base its evaluation of such progress on, among other things, the following:
 - 1. the rate of refusal by HHS/FDA of Drugs, Excipients, and Medical Devices exported from the customs territory of China and offered for import into the United States, as compared to the overall rate of refusal in calendar year 2007 or other relevant period by HHS/FDA of Drugs, Excipients, and Medical Devices exported from the customs territory of China and offered for import into the United States; and

2. the volume, frequency and significance in terms of public health hazard of recalls of Drugs, Excipients, and Medical Devices in the United States, including Counterfeit Drugs and Medical Devices, exported from the customs territory of China and offered for import into the United States as compared to the volume, frequency and significance of such recalls in 2007 or other relevant period.
- B. SFDA may base its evaluation of such progress on, among other things, the following:
1. a rate of refusal of Designated Drugs and Designated Medical Devices approved by HHS/FDA offered for import into the customs territory of China, as compared to the overall rate of refusal in the previous calendar year;
 2. the overall percentage of Designated Drugs and Designated Medical Devices exported from the customs territory of the United States and offered for import into the customs territory of China that are determined as unqualified based on the supervised sample testing; and
 3. the volume frequency, and significance in terms of public health hazard of recall of drugs and medical devices in China, including Counterfeit Drugs and Medical Devices, exported from the United States and offered for import into the customs territory of China as compared to the volume, frequency and significance of such recalls in the previous calendar year.

Article IX Final Provisions

- A. Nothing in this Agreement precludes the Government of United States or the Government of China from taking any measure to protect the public health or the citizens of its respective country. HHS/FDA and SFDA affirm that it shall work with its country's national, state, provincial, or municipal bodies, as appropriate, to implement this Agreement fully.
- B. Nothing in this Agreement shall be construed to affect the rights or obligations of the United States or China under any other agreement in force between the United States and China.
- C. HHS/FDA actions with regard to Drugs, Excipients, and Medical Devices shall be governed by HHS/FDA Requirements and all other existing U.S. laws and regulations.

- D. SFDA actions with regard to Drugs, Excipients, and Medical Devices shall be governed by SFDA Requirements and all other existing Chinese laws and regulations.
- E. The Parties shall endeavor to resolve any dispute regarding the implementation or interpretation of this Agreement through timely consultations.
- F. This Agreement shall enter into force upon signature by both Parties and shall remain in force for a period of two years, unless terminated by either Party. On the last day of the two-year period, and of each subsequent two-year period, the Agreement shall automatically be renewed for another two-year period, unless either Party notifies the other Party that it wishes to terminate the Agreement at least 60 calendar days prior to the last day of the two-year period. In addition, either Party may terminate the Agreement upon 60 calendar days' written notice to the other Party. The Parties may amend this Agreement at any time by mutual written agreement.

DONE at Beijing, this 11th day of December, 2007, in duplicate in the English and Chinese languages, each text being equally authentic.



FOR THE DEPARTMENT OF HEALTH
AND HUMAN SERVICES OF THE
UNITED STATES OF AMERICA



FOR THE STATE FOOD AND
DRUG ADMINISTRATION OF THE
PEOPLE'S REPUBLIC OF CHINA