

IMPLEMENTING ARRANGEMENT
BETWEEN THE
FOOD AND DRUG ADMINISTRATION
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OF THE
UNITED STATES OF AMERICA
AND THE
CHINA FOOD AND DRUG ADMINISTRATION
OF THE PEOPLE'S REPUBLIC OF CHINA
REGARDING THE COOPERATIVE MECHANISM OF
REGULATORY STAFF

The Food and Drug Administration (U.S. FDA) of the Department of Health and Human Services of the United States of America and the China Food and Drug Administration (CFDA) of the People's Republic of China (hereinafter referred to together as "the Participants"):

Recalling the Agreement between the Department of Health and Human Services of the United States of America and State Food and Drug Administration of the People's Republic of China on the Safety of Drugs and Medical Devices (the "Agreement") signed on December 11, 2007,

Noting that the U.S. FDA and CFDA share the understanding that the State Food and Drug Administration of the People's Republic of China (SFDA) was reorganized in 2013, and CFDA has become the successor in interest to SFDA of the commitments in the Agreement;

Noting that both Participants share the understanding that, in light of the above, all references to the State Food and Drug Administration of the People's Republic of China in the Agreement are henceforth understood to refer to the CFDA;

Aiming to identify the scope of activities to be conducted under the Agreement by U.S. FDA and CFDA regulatory personnel posted in one another's country;

Desiring to further set out the framework for exchange of information and documents under Article V of the Agreement related to observations and results from inspections of facilities that are engaged in manufacturing, producing, processing, packing, testing, holding, transporting, distributing, or exporting any Drug (which term, as used throughout this (IA), includes active pharmaceutical ingredients, as under the Agreement);

Recognizing that this IA lays out a means through which each agency can obtain information to inform its regulatory decision-making; and

Realizing that this IA further clarifies the intentions of the Participants under the Agreement by which each Participant may save time and costs in meeting its statutory requirements without a reduction of public health and safety or regulatory responsibilities;

Intend to further implement the Agreement as follows:

SECTION I INSPECTION AND COOPERATION BY U.S. FDA REGULATORY PERSONNEL POSTED IN CHINA

1. U.S. FDA intends to continue to conduct inspections in China to assess the compliance with relevant U.S. requirements of facilities that are engaged in manufacturing, producing, processing, packing, testing, holding, transporting, or distributing any Drug intended for export to the United States or its territories. In support of these inspections, FDA may also collect and analyze product samples.
2. For other than for-cause inspections conducted by U.S. FDA regulatory personnel posted in China, U.S. FDA intends to provide CFDA at least five working days' advance notice regarding its intent to inspect and the relevant facility's name and location. In an effort to promote better understanding of U.S. FDA's inspectional programs and techniques, and to promote cooperative efforts to ensure the safety of any

Drug, U.S. FDA intends to invite CFDA personnel to accompany said U.S. FDA personnel on other than for-cause inspections. As appropriate, U.S. FDA may also use this process to invite CFDA regulatory personnel posted in the United States to join a certain number of U.S. FDA pharmaceutical inspections in the United States each year.

3. U.S. FDA intends to provide CFDA with timely notification regarding manufacturing conditions or products that may constitute potential hazards to health or violations of applicable U.S. regulations. This notification may include, as deemed appropriate by U.S. FDA, the exchange of redacted recall information, adverse product trends, warning letters, copies of FDA's Form 483, and information from import alerts.
4. As appropriate, U.S. FDA intends to provide, in a timely manner, redacted copies of establishment inspection reports from inspections conducted in China and product sample results that U.S. FDA deems appropriate.
5. When CFDA finds a hazard to health, and U.S. FDA concurs with this assessment, U.S. FDA may, where appropriate, conduct a follow-up inspection in an expedited manner, and provide CFDA with written findings from its inspection.
6. On an ongoing basis, U.S. FDA intends to provide CFDA information on firms registered under the U.S. drug regulatory system, including information regarding products firms produce, through electronic databases or information platforms, or through hard-copy records where no electronic data exist.
7. U.S. FDA intends to identify to CFDA a primary point of contact for carrying out activities under this IA. This point of contact holds primary responsibility for communication and coordination related to inspection notifications; requests for inspection reports; and follow-up regarding compliance actions, recalls, alerts, adverse event reports, and meetings.

**SECTION II INSPECTION AND COOPERATION BY CFDA REGULATORY PERSONNEL
POSTED IN THE UNITED STATES OF AMERICA**

1. CFDA intends to continue to conduct inspections in the United States to assess the compliance with relevant Chinese requirements of facilities that are engaged in manufacturing, producing, processing, packing, testing, holding, transporting, or distributing any Drug intended for export to China. In support of these inspections, CFDA may also collect and analyze product samples.
2. For other than for-cause inspections conducted by CFDA regulatory personnel posted in the United States, CFDA intends to provide U.S. FDA at least five working days' advance notice regarding its intent to inspect and the relevant facility's name and location. In an effort to promote better understanding of CFDA's inspectional programs and techniques, and to promote cooperative efforts to ensure the safety of any drugs, CFDA intends to invite U.S. FDA personnel to accompany said CFDA personnel on other than for-cause inspections. As appropriate, CFDA may also use this process to invite U.S. FDA personnel posted in China to join a certain number of CFDA pharmaceutical inspections in China each year.
3. CFDA intends to provide U.S. FDA with timely notification regarding manufacturing conditions or products that may constitute potential hazards to health or violations of applicable Chinese regulations. This notification may include, as deemed appropriate by CFDA, the exchange of redacted recall information, adverse product trends, warning letters, copies of relevant CFDA inspection reports, and information from import measures put in place by CFDA.
4. As appropriate, CFDA intends to provide, in a timely manner, redacted copies of inspection reports from inspections conducted in the United States and product sample results that CFDA deems appropriate.
5. When U.S. FDA finds a hazard to health, and CFDA concurs with this assessment, CFDA may, where appropriate, conduct a follow-up inspection in an expedited manner, and provide U.S. FDA with written findings from its inspection.

6. On an ongoing basis, CFDA intends to provide U.S. FDA information on firms registered under China's drug regulatory system, including information regarding products firms produce, through electronic databases or information platforms, or through hard-copy records where no electronic data exist.
7. CFDA intends to identify to U.S. FDA a primary point of contact for carrying out activities under this IA. This point of contact holds primary responsibility for communication and coordination related to inspection notifications; requests for inspection reports; and follow-up regarding compliance actions, recalls, alerts, adverse event reports, and meetings.

SECTION III OTHER PROVISIONS

This IA does not affect existing arrangements between the Participants, including the Agreement.

Nothing in this IA diminishes or otherwise affects the authority of either Participant to carry out its respective statutory functions within its own territory. Additionally, no provision of this IA restricts either Participant from making its own, otherwise permitted inspection of any pharmaceutical facility located within the jurisdictional boundaries of the other country when needed to meet the needs of its own program for the regulation of pharmaceutical products.

Nothing in this IA creates binding obligations between the Participants. All activities undertaken pursuant to the IA are subject to the availability of appropriated funds, personnel, and other resources. The terms of the Agreement, and all terms herein that are defined in the Agreement have the same meanings as in the Agreement. Each Participant is expected to fund its own activities under the IA unless the Participants agree otherwise.

Cooperative activities under this IA may commence upon signature and are intended to automatically renew, so long as the Agreement is in force, for successive periods of five (5) years unless discontinued by either Participant. A Participant intending such discontinuation should endeavor to provide at least sixty (60) days written notification to the other Participant

prior to the last day of any given five year period. This IA may be modified by written mutual consent of both Participants.

Signed in *Beijing* on *the 21st* day of *November*, ²⁰¹⁴ in duplicate in the English and Chinese languages, both texts being equally authentic.

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FOR ~~THE~~ FOOD AND DRUG
ADMINISTRATION,
DEPARTMENT OF HEALTH AND
HUMAN SERVICES
OF THE UNITED STATES OF AMERICA

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