Procedures for Joint-Review Meetings after Pharmaceutical Manufacturing Site Inspection
(Interim)

I. The Procedures is developed with the view of regulating the management and improving the quality & efficiency of joint-review meetings after pharmaceutical manufacturing site inspection (hereinafter referred to as the "Joint-Review Meeting").

II. The joint-review meeting refers to the meetings organized by the Office of Management and Communication, with attendees of relevant office of pharmaceutical science, review reporting office, testing institute and inspection and auditing unit, to address inconsistent conclusions or significant decision making issues that call for communication, in the process of comprehensive review of the production site inspection reports, site sampling testing reports as well as the technical review reports (referred to as the "3-in-1 Review").

III. The Office of Management and Communication is responsible to propose joint-review meeting applications, and to clarify the issues to be discussed, the attendees, time and venue of meetings, the organization and implementation of which can be started with the approval of CDE leadership.

IV. Attendees of the joint-review meeting:

(A) Related staff of office of management and communication, chief reviewer of office of pharmaceutical science, director or deputy director of related office, and personnel of production site inspection departments and / or drug testing institution generally should participate in the meeting.

(B) Director or deputy director of the review reporting office, the CDE leaders, and relevant staff of SFDA departments may attend the meeting as appropriate.

(C) The applicants for drug registration may be invited to attend the meeting if necessary.
V. The joint-review meeting shall be presided over by relevant staff of the Office of Management and Communication.

VI. The joint-review meeting shall come to management suggestions and explicit conclusions. The meeting minutes shall be rewritten by relevant staff of the Office of Management and Communication, or CMC chief reviewer if necessary, and shall be submitted to the Director of Office of Management and Communication for checking.

The Office of Management and Communication is responsible to submit the meeting minutes to the production site inspection departments and drug testing institution attending the meeting for discussion and confirmation.

If the conclusions of the joint-review meeting are inconsistent with which of the production site inspection and / or testing, the meeting minutes must be countersigned by the above-mentioned units.

The meeting minutes should be attached as the Annex of the "3-in-1" Comprehensive Review Opinions.

VII. The Office of Management and Communication is responsible for drafting the "3-in-1" comprehensive review opinions and review conclusions on the basis of the opinions and conclusions of the joint-review meeting, developing documents for approval and submitting to the CDE leadership for signing off.

VIII. All relevant CDE staff should abide by the Procedures.

IX. The Procedures shall enter into force as of the date of release.

Annex: Plan of the Joint-Review Meeting
### Annex:

**Plan of the Joint-Review Meeting**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Accepted Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review Reporting Office</td>
<td>The Applicant Company</td>
</tr>
<tr>
<td>CMC chief reviewers</td>
<td>Production Site Inspection Units / Sample Testing Units</td>
</tr>
</tbody>
</table>

- **Overview of the Drug and Review**
- **Issues to be Discussed**
- **The Purpose of the Meeting**
- **Necessary Attendees**
  - CDE staff:
  - Staff of units:
  - The applicants for registration:
  - Expert requirements:
  - Others:

- **Intended Date of the Meeting**
- **Intended Venue of the Meeting**
- **The Opinion of the Office of Management and Communication**
- **Opinion of CDE leadership**
- **Notes**

**Disclaimer:**
This document is for reference only. For any dispute, the Chinese version shall prevail.