FINAL REPORT


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Submitted by:

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Final Report

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Executive Summary

A quality assurance evaluation and monitoring program was implemented by Family Health International to verify that Sino-implant (II) meets lot release specifications for the product and to evaluate if the product meets international quality standards. This report expands on the results obtained after the initial quality assurance evaluation and monitoring program conducted in 2008.

Commercial lot release testing verification was conducted for four lots of Sino-implant (II) that were shipped to countries as part of the Sino-implant (II) introduction in developing countries. In all instances results were in compliance with Sino-implant (II) lot release specifications (Table 1). Process Capability Analysis (Cpk) was performed using historical lot release data from the product manufacturer. The process capability statistics were used to compare the levonorgestrel dissolution and assay results to the specifications.

A more extensive battery of tests was conducted to evaluate if Sino-implant (II) meets international quality standards. The battery of tests selected was based on standards from the United States Pharmacopeia (USP), International Organization for Standardization (ISO) and the American Society for Testing and Materials (ASTM). Sino-implant (II) samples tested met the quality requirements for all tests conducted (Table 1).

We conclude that Shanghai Dahua Pharmaceutical Co., Ltd continues to demonstrate the ability to consistently produce a contraceptive implant that meets international quality standards.
### Table 1. Summary of the quality assurance evaluation of Sino-implant (II)

<table>
<thead>
<tr>
<th>Test</th>
<th>Lot #</th>
<th>Results</th>
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<tr>
<td><strong>Quality Assurance Monitoring of Sino-implant (II)</strong></td>
<td></td>
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<tr>
<td>Sino-implant (II): Commercial Lot Release Testing</td>
<td>09182008 04062009 04192009 05172009</td>
<td>Met requirements</td>
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<td>Verification</td>
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<td><strong>Annual Quality Assurance Evaluation of Sino-implant (II)</strong></td>
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<td>Levonorgestrel: Active Ingredient Quality Assurance Evaluation</td>
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<td>Levonorgestrel: China Pharmacopeia Evaluation</td>
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<td>Levonorgestrel: USP Evaluation</td>
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<td>Sino-implant(II) : Final Product Quality Assurance Evaluation</td>
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<tr>
<td>Sample Lot Release Verification</td>
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<td>Ethylene Oxide Residuals Evaluation</td>
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<td>Cytotoxicity Evaluation</td>
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<td>Sino-implant(II) : Packaging Material Evaluation</td>
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<td>Packaging Physicochemical Evaluation</td>
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<td><strong>Note:</strong></td>
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</tr>
<tr>
<td>a Conducted by SGS Life Sciences Division, Shanghai, China</td>
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<td>b Conducted by Nelson Laboratories, Inc., Salt Lake City, UT</td>
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<td>c Conducted by Azopharma, Maryland Heights, MO</td>
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<td>d Conducted by Irvine Pharmaceutical Sciences, Irvine, CA</td>
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