FINAL REPORT


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Submitted by:

Family Health International

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Final Report

Family Health International

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Executive Summary

A quality assurance evaluation of the contraceptive implant Sino-implant (II) was conducted by Family Health International to verify that Sino-implant (II) meets international quality standards.

Lot release testing was verified for 10 lots of Sino-implant (II) and in all instances results were in compliance with Sino-implant (II) lot release specifications (Table 1). A more extensive quality evaluation of Sino-implant (II) was conducted using standards and tests 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 Dahua Pharmaceuticals is capable of producing an implant that meets international quality standards. In addition, we now have established a baseline on the Sino-implant (II) product to evaluate the continued quality of the product.

Table 1. Summary of the quality assurance evaluation of Sino-implant (II)

<table>
<thead>
<tr>
<th>Test</th>
<th>Lot #</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sino-implant (II): Lot Release Verification</td>
<td>15082007(^a) 071008(^a,b) 071023(^a,b) 071104(^a,b) 071206(^a,b) 080408(^a,b) 080507(^a,b) 080527(^a,b) 080624(^a,b) 080715(^a,b) 080902(^b)</td>
<td>Met requirements</td>
</tr>
<tr>
<td>Levonorgestrel Lot Release Verification(^b)</td>
<td>ZQ20080006 ZQ20080012 ZQ20080016</td>
<td>Met requirements</td>
</tr>
<tr>
<td>Sino-implant (II): Ethylene Oxide Residuals</td>
<td>071008 071023 071104</td>
<td>Met requirements</td>
</tr>
<tr>
<td>Evaluation(^c)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sino-implant (II): Metal Impurities Evaluation(^d)</td>
<td>071008 071023 071104</td>
<td>Met requirements</td>
</tr>
<tr>
<td>Sino-implant (II): Residual Solvents Evaluation(^e)</td>
<td>071008 071023 071104</td>
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<tr>
<td>Sino-implant (II): Packaging Impurities Evaluation(^f)</td>
<td>DK10666500259A1</td>
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<td>Sino-implant (II): Bacterial Endotoxin Testing(^g)</td>
<td>071008 071023 071104</td>
<td>Met requirements</td>
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FHI CONFIDENTIAL INFORMATION
<table>
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<th>Test</th>
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<th>Result</th>
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<tr>
<td>Sino-implant (II): Cytotoxicity&lt;sup&gt;c&lt;/sup&gt;</td>
<td>071206, 080408, 080527</td>
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<tr>
<td>Sino-implant (II): Package Integrity Evaluation&lt;sup&gt;c&lt;/sup&gt;</td>
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<td>Met requirements</td>
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</tbody>
</table>

<sup>a</sup>Conducted by FHI Product Quality and Compliance Division, Research Triangle Park, NC

<sup>b</sup>Conducted by SGS Life Sciences Division, Shanghai, China

<sup>c</sup>Conducted by Nelson Laboratories, Inc., Salt Lake City, UT

<sup>d</sup>Conducted by Cyanta Analytical Laboratories, Maryland Heights, MO

<sup>e</sup>Conducted by Irvine Pharmaceutical Sciences, Irvine, CA