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 FHI 360 to verify that Sino-implant (II) meets lot release specifications for the product. This report expands on the results obtained after the quality assurance evaluation and monitoring program conducted from 2008 to 2011.

Commercial lot release testing verification was conducted for all eight 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).

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), British Pharmacopeia (BP), 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)

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<th>Test</th>
<th>Lot #</th>
<th>Results</th>
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</table>

\(^a\) Conducted by SGS Life Sciences Division, Shanghai, China
\(^b\) Conducted by Nelson Laboratories, Inc., Salt Lake City, UT
\(^c\) Conducted by EAG-Life Sciences, Maryland Heights, MO
\(^d\) Conducted by Irvine Pharmaceutical Sciences, Irvine, CA
\(^e\) Conducted by Lancaster Laboratories, Lancaster, PA