FINAL REPORT


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FHI 360

Markus Steiner, Ph.D.
Sino-implant (II) Project Director
Family Health International
P.O. Box 13950
Research Triangle Park, NC 27709
Tel: +1.919.544.7040
FAX: +1.919.544.7261
Final Report

FHI 360

David W. Jenkins, Ph.D.
Associate Scientist II
Product Quality and Compliance Department
2810 Meridian Parkway, Suite 133
Durham, NC 27713
E-mail: djenkins@fhi360.org
Phone: 919-544-7040 ext. 11617
Fax: 919-544-5849

Derek H. Owen, Ph.D.
Scientist I
Clinical Sciences
2224 E. NC Hwy. 54, Durham NC 27713
E-mail: dowen@fhi360.org
Telephone: 919-544-7040 ext. 11168
Fax: 919-544-7261

Markus Steiner, Ph.D.
Sino-implant (II) Project Director
Clinical Sciences
2224 E. NC Hwy. 54, Durham NC 27713
E-mail: msteiner@fhi360.org
Telephone: 919-544-7040 ext. 11346
Fax: 919-544-7261
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Executive Summary

A quality assurance evaluation and monitoring program was implemented by FHI 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 in 2008, 2009 and 2010.

Commercial lot release testing verification was conducted for all nine 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)

<table>
<thead>
<tr>
<th>Test</th>
<th>Lot #</th>
<th>Results</th>
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<tr>
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<td>Sino-implant (II): Final Product Quality Assurance Evaluation</td>
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\( ^{a} \) 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