FINAL REPORT

Sino-implant (II) Initiative: 2012 Quality Assurance Evaluation

December 15, 2012

Submitted by:

FHI 360

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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)

Test		Lot #	Results
Quality Assurance Monitoring of Sino-implant (II)			
Sino-implant (II): Commercial Lot Release Testing Verification[a]		**07112001 05162012 06082012 06272012 07132012 08032012 09152012 10072012**	**Met requirements**
Annual Quality Assurance Evaluation of Sino-implant (II)			
Levonorgestrel: Active Ingredient Quality Assurance Evaluation	**Levonorgestrel: China Pharmacopeia Evaluation**[a]	**ZQ20120002 ZQ20110016 ZQ20110022**	**Met requirements**
	Levonorgestrel: British Pharmacopeia Evaluation[e]		**Met requirements**
Sino-implant(II) : Final Product Quality Assurance Evaluation	**Sample Lot Release Verification**[a]	**09022012 24022012 10032012**	**Met requirements**
	Ethylene Oxide Residuals Evaluation[b]		**Met requirements**
	Inorganic Impurities Evaluation[c]		**Met requirements**
	Residual Solvents Evaluation[d]		**Met requirements**
	Bacterial Endotoxin Evaluation[b]		**Met requirements**
	Cytotoxicity Evaluation[b]		**Met requirements**
Sino-implant(II) : Packaging Material Evaluation	**Packaging Physicochemical Evaluation**[b]	**11-071PA1-11-OP-22-1 11-071P-11-8-23-1 110117**	**Met requirements**
	Sino-implant (II): Package Integrity Evaluation[b]	**09022012 24022012 10032012**	**Met requirements**

[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