FINAL REPORT

Sino-implant (II) Initiative: 2011 Quality Assurance Evaluation

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Submitted by:

FHI 360

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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)

Test		Lot #	Results
Quality Assurance Monitoring of Sino-implant (II)			
Sino-implant (II): Commercial Lot Release Testing Verification[a]		**11092010 02102011 03252011 04122011 05092011 05262011 06132011 08092011 10262011**	**Met requirements**
Annual Quality Assurance Evaluation of Sino-implant (II)			
Levonorgestrel: Active Ingredient Quality Assurance Evaluation	**Levonorgestrel: China Pharmacopeia Evaluation**[a]	**ZQ201101014 ZQ201101015 ZQ20100018-3**	**Met requirements**
	Levonorgestrel: British Pharmacopeia Evaluation[e]		**Met requirements**
Sino-implant(II) : Final Product Quality Assurance Evaluation	**Sample Lot Release Verification**[a]	**01122010 11092010 16122010**	**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]	**(09-1143)-10-22-1 (11-0719A)-11-9-22-1 (11-0719)-11-8-21-1**	**Met requirements**
	Sino-implant (II): Package Integrity Evaluation[b]	**01122010 11092010 16122010**	**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