FINAL REPORT

Sino-implant (II) Initiative: 2013 Quality Assurance Evaluation

December 15, 2013

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 2012.

Commercial lot release testing verification was conducted for all six 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). With exception to one (1) newly refined 2013 BP standard, the Sino-implant (II) samples tested met the quality requirements for all tests conducted (Table 1).

In working to meet all international quality standards, we are currently undergoing the qualification of a new API supplier to ensure the more stringent 2013 BP specification can be met.

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

Test		Lot #	Result
Quality Assurance Monitoring of Sino-implant (II)			
Sino-implant (II): Commercial Lot Release Testing Verification[a]		**01082013 01212013 05072013 05282013 06302013 09152013**	**Met requirements**
Annual Quality Assurance Evaluation of Sino-implant (II)			
Levonorgestrel: Active Pharmaceutical Ingredient Quality Assurance Evaluation	**Levonorgestrel: China Pharmacopeia Evaluation**[a]	**ZQ20120012 ZQ20130002 ZQ20130003**	**Met requirements**
	Levonorgestrel: 2011 British Pharmacopeia Evaluation[e]		**Met requirements**
	Levonorgestrel: 2013 British Pharmacopeia Evaluation[e]		**Met requirements with exception of related substances**
Sino-implant(II) : Final Product Quality Assurance Evaluation	**Sample Lot Release Verification**[a]	**10112012 07102012 20102012**	**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]	**11-0719A-1-11-9-22-1 11-0719-11-8-23-1**	**Met requirements**
	Sino-implant (II): Package Integrity Evaluation[b]	**10112012 07102012 20102012**	**Met requirements**

[a] Conducted by SGS Life Sciences Division, Shanghai, China
[b] Conducted by Nelson Laboratories, Inc., Salt Lake City, UT
[c] Conducted by SGS Life Sciences Division, Lincolnshire, IL
[d] Conducted by Irvine Pharmaceutical Sciences, Irvine, CA
[e] Conducted by Lancaster Laboratories, Lancaster, PA