From: Berry, Michelle (Marlborough)
Sent: 07/23/2008 03:11:22 PM
To: McGrath, Janet
Subject: Marlex MSDS Response.doc
Attachments: image001.gif

FDA Question # 8

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The material safety data sheet (MSDS) provided for the Marlex material states that the product use is for coatings. In this MSDS there is a medical application caution that states "do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." Please provide a rationale why your mesh material is safe for use as a permanent implant device contrary to what is stated in the MSDS provided for the Marlex material.

BSC Response:

Background:

Marlex HGX-030-01 Polypropylene Homopolymer resin has been used by Boston Scientific for permanent implant since the late 1990's. From the late 1990's until early 2002, the resin was purchased from Philips Sumika and spun into fiber at Shakespeare Monofilament (acquired by Jarden in April 2007).

In 2002 Boston Scientific was informed that Philips Sumika no longer would supply this resin for any application involving implantation in the human body due to the company's unwillingness to accept any liability for the use of their resin for medical purposes – particularly permanent implants. They subsequently revised the MSDS for Marlex HGX-030-01 to this effect.

However, in 2004, Boston Scientific entered into a 1 year contract with Philips Sumika to enable Boston Scientific Corporation to purchase the resin with the understanding that Boston Scientific would use this material in the manufacture of medical devices which may be implanted in the human body. The agreement required Boston Scientific to be ultimately responsible for ensuring that the material is suited to the specific application and assume all product liability.

EXHIBIT
38B

Boston Scientific expected the contract to be renewed at yearly intervals. However, Chevron's[B1] intent was to allow Boston Scientific to purchase one last order of material before the initial contract expired – with no plans to renew the contract. A large order of resin was placed in late July 2005 and we have not yet depleted the supply. A redacted copy of the contract is presented in Appendix D.

Boston Scientific has performed extensive testing to support that the material is safe for use as a long term, permanent implant device.

Safety Testing:

A full battery of biocompatibility tests was conducted on mesh made from the Marlex HGX-030-01 resin in accordance with ISO 10993 for a long term permanent implant device. The biocompatibility tests performed are listed on the next page.

- Ames Mutagenicity / Part 3
- Mouse Lymphoma / Part 3
- Cytotoxicity MEM Elution/ Part 5
- Implantation / Part 6
- USP Physicochemical test for Plastics <661>
- Guinea Pig Maximization Sensitization / Part 10
- Intracutaneous Reactivity/ Part 10
- Acute Systemic Injection/ Part 11
- Sub Acute Toxicity/ Part 11

When evaluated according to the above listed biocompatibility standards, the Mesh material is considered biocompatible for its intended use as indicated by results for Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Genotoxicity, Implantation, and USP Physicochemical. The summary of biocompatibility data was provided in K081048, Section 15.

In addition, a rabbit implantation study was commissioned by Boston Scientific to assess the safety of a Boston Scientific polypropylene mesh made from Marlex HGX-030-01. Dr. Badylak's report, dated Jan 13, 2003 confirmed that the mesh made from Marlex HGX-030-01 had physiological response comparable to the control device, a competitive implantable mesh also made from polypropylene (confirmed by FTIR). See Appendix D.

Shelf Life:

Although the product shelf life for the proposed device is to be labeled 1 year at time of launch, additional shelf life test data is available on a similar mesh product made with the same Marlex resin. Results of mesh product performance following three years of real time age conditioning demonstrate that long term aging conditions do not negatively affect the performance results of the mesh material.

In addition, while formal shelf life studies have not been conducted on the resin as supplied by the manufacturer, the literature suggests that polypropylene does not have a limit to its shelf life when stored under reasonable conditions. Boston Scientific has opted to put a 10 year shelf life on the resin and a 7 year shelf life on the fiber – with recertification required beyond 7 years.

In addition each batch of yarn is tested for the following characteristics prior to manufacturing the mesh knit:

Characteristic

Unit

Value

Tolerance

Denier

DEN

77.5

± 3.0

Outer Diameter

micron

109

± 4

Tensile Strength

N

4.5

Min

Tensile Strength Maximum Extension

%

19

7

Knot Strength

N

4

1.2

Shrinkage

%

7

2

Summary:

Marlex HGX-030-01has been safely used for permanent implant for over 10 years. There is sufficient knowledge and history with this resin to assure that the resin and fiber properties are stable over time and therefore safe.

[B1]Phillips Sumika's