

P030053 9/30/04 Post Approval Study Responses

-----Original Message-----

From: Free, Donna [mailto:DFree@mentorcorp.com]
Sent: Thursday, September 30, 2004 6:55 PM
To: 'Allen, Samie Niver'
Cc: Michael, Maher
Subject: FW: P030053 - postapproval study

Samie,

Below, please find Mentor's responses to FDA's issues regarding the postapproval study. We hope that this information is adequate.

Thanks

Donna

-----Original Message-----

From: Allen, Samie Niver [mailto: SXN@CDRH.FDA.GOV]
Sent: Thursday, September 23, 2004 1:03 PM
To: 'Free, Donna'
Cc: 'Michael, Maher'
Subject: P030053 - postapproval study

Donna,

Here is feedback on this issue (37c). Thanks, Samie

You stated that you do not believe that a separate postapproval study is necessary. However, FDA does not agree with this. While you may be proposing no change in the data collection, there is a different purpose to a postapproval study than a premarket study. Investigators and patients need to know that there has been a status change but that the study continues. Therefore, please provide a draft postapproval study that includes the following:

1. An Investigator Agreement addendum that states the purpose of the postapproval study and requires signature of the investigator. This will better assure that the investigators are well aware of the change in status of your device yet the continued required patient follow-up.

1 Response:

An addendum to the Investigator Agreement has been developed and is included in this response. This addendum explains that the Mentor Silicone Gel-Filled Breast Implants have been approved by FDA and the Core Gel study has been converted to a postapproval study. Each Investigator will sign the addendum, retain a copy for his/her study files, and send a copy to Mentor.

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2. If there are any protocol changes, then a description of any changes and copies of any revised CRFs. You should consider incorporating some level of follow-up on patients who have all devices removed with no replacement, rather than discontinuing these patients. You should also consider whether or not you need to modify the monetary incentives to keep investigators/patients after PMA approval.

2 Response:

No changes will be made to the Core Gel protocol. Mentor does not believe that it is necessary to follow patients after all study devices are explanted, as available data indicate that there are no health consequences associated with intact or ruptured implants. Moreover, it is unlikely that patients who no longer are implanted with Mentor devices would be willing to return for follow-up visits.

Mentor thinks that Investigator and subject monetary incentives are adequate (see the subject compensation table below). We will closely monitor subject follow up rates, and will revisit this issue if the follow up rates decrease significantly.

**Subject Compensation for
Years 4 Through 10**

Visit	Payment
4 year visit	\$150.00
5 year visit	\$150.00
6 year visit	\$150.00
7 year visit	\$150.00
8 year visit	\$150.00
9 year visit	\$150.00
10 year visit	\$150.00
Total	\$1,050
Total – bonus*	\$1,300

* If subject misses no postoperative visits, she receives a bonus of \$250

3. An Informed Consent addendum that states the purpose of the postapproval study and requires signature of the patient. A description of any changes to the types of follow-up visits, monetary incentives, etc. should be described.

3 Response:

At their first exam after approval of the Mentor Silicone Gel-Filled Breast Implants, each subject will be given a letter that explains the status of the clinical study they have been participating, and the conversion of the status to pre-approval versus post-approval. The purpose of the postapproval study will be stated and the patients will be reminded of their commitment to continue to come back for all postoperative exams through ten years. Each subject will sign the letter, attesting that she received a copy. The original signed

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letter will be kept in the subject's study files and a copy will be sent to Mentor. A copy of the letter is included in this response.

4. Dissemination of the approved patient labeling/package labeling to the investigators and patients.

4 Response:

After Mentor Silicone Gel-Filled Breast Implants are approved, the updated labeling will be included in each gel implant packaged by Mentor that will be shipped to the physicians. Mentor will also make available at physician offices approved copies of the Patient Informed Decision Brochure. Additionally, Mentor will post the updated patient labeling/package labeling on its website. We know that FDA will post this same information, along with other relevant breast implant related documents on the FDA website.

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