Seventy-Fourth Meeting of the
Obstetrics and Gynecology Devices Panel
Thursday, December 11, 2008
Holiday Inn, Gaithersburg, MD

Female Health Company- FC2 Female Condom (P080002)
DRAFT Discussion Questions

Contraceptive Effectiveness Study

1. FDA approved the first female condom (FC1) in 1993 based on a multi-center single-arm contraceptive effectiveness study, and FC2 represents a new version of this condom. The sponsor submitted results from a clinical study comparing FC1 and FC2 (RHRU Study); this study used a randomized cross-over design and was based on user self-reports with respect to four defined *in-use* failure modes:

    - breakage,
    - invagination,
    - misdirection, and
    - slippage.

    The sponsor asserts that this study shows that FC2 is functionally equivalent to FC1, and, therefore, that FC2 will be just as effective in preventing pregnancy, HIV/AIDS, and other common sexually transmitted infections (STIs). The sponsor asserts that a study of clinical outcomes (e.g., pregnancy, STIs) is not necessary for FC2 approval.

    Please discuss whether an acute performance outcomes study, i.e., a failure modes study, provides reasonable assurance of safety and effectiveness of a female condom.

Comparison Study between FC1 and FC2 (RHRU Study)

2. As described above, the pivotal clinical study supporting approval of this PMA is based on user self-reports and compares the events rates between FC1 and FC2 for four defined failure modes:

    - breakage,
    - invagination,
    - misdirection, and
    - slippage.

    Please discuss the impact of the following on data reliability.

    a. The study outcomes data collected for analysis were based on interviews between a clinical investigator and the subject, not the data from the coital log itself. Interviews were sometimes conducted weeks or months after actual condom use. Please discuss the potential impact on data reliability when events are not reported promptly after each sex act. Also, please discuss the potential impact of expectation bias by using data from interviews instead of coital logs.

    b. Twenty-one percent (59/276) of the study subjects in the RHRU Study were commercial sex workers (CSWs). Some previous studies of condom use by CSWs have reported very low condom failure rates.

c. Thirty-eight percent (168/436) of the interviews were conducted without coital logs, which were intended to be used as memory prompts.

d. The coital logs did not have an entry field to capture data on slippage.

e. The coital logs were not designed to capture data if more than one condom was used in a given day.

3. The following is a key data table from the PMA showing the comparative event rates of breakage, mis-direction, invagination, and slippage for users of FC1 and FC2.

Failure Mode	**FC1**		**FC2**		***difference*** ---------- ***FC2 – FC1***
	events/total used	%	events/total used	%	
breakage	9/1910	0.47	8/1881	0.43	-0.04 (-0.62 to 0.53)
mis-direction[1]	24/1910	1.26	12/1881	0.64	-0.62 (-1.33 to 0.09)
invagination[2]	10/1910	0.52	17/1881	0.90	0.38 (-0.25 to 1.01)
slippage[3]	4/1910	0.21	2/1881	0.11	-0.10 (-0.39 to 0.19)
total failures	47/1910	2.46	39/1881	2.07	-0.39 (-1.67 to 0.89)

[1] Misdirection is actually recorded as "Incorrect Penetration" in the PMA (page 4-1519).
[2] Invagination is actually recorded as "Outer Ring Displacement" in the PMA (page 4-1519).
[3] FDA NOTE: Data on Slippage *per se* was collected neither on the subject's Coital Log, nor on the staff questionnaire.

For each individual failure mode, the upper bound on the confidence interval for the difference between FC2 and FC1 is $\leq$ 1.0%. Please discuss whether the data shows that the FC2 is safe and effective when used for barrier protection against pregnancy and sexually transmitted infections.

Labeling

4. The sponsor provided patient labeling for the FC2 Female Condom.

a. What information regarding female condom failure modes should be included in the labeling?

b. Does the panel have any other comments regarding labeling?

Post-market Plan

6. The sponsor is proposing to meet the post-approval requirements typically required for any PMA approval, including procedures for

   - Quality Release,
   - Medical Device Reporting (MDR),
   - Product Recall,
   - Traceability, and
   - Corrections and Removals.

   In addition, the sponsor will submit reports annually on changes to and literature regarding the device.

   The sponsor does not propose to conduct any postmarket studies. Please note that post-approval studies are typically used to evaluate long-term, real world uses of devices, or capture rare events that would not typically be evident in premarket studies. Post-approval studies should not be used to evaluate unresolved issues from the premarket phase that are important to the initial establishment of device safety and effectiveness.

   Please comment on whether the sponsor's postmarket plan is appropriate for this kind of device.