



Office of the Director
Division of Practice Activities
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August 26, 1997

Kimber C. Richter, MD
Deputy Director, Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Dear Dr. Richter:

Our previous discussions regarding the FDA's approval process for labeling of devices have been most helpful in increasing ACOG's understanding of the approval of these devices. Recently, some concern has been raised regarding a possible change in FDA's premarketing approval of home uterine activity monitoring devices which could have implications for other devices as well. Larry Gilstrap, MD, chair of ACOG's Committee on Obstetric Practice, has discussed the issue with Colin Pollard and Lillian Yin, PhD.

You and I had previously discussed having representation at relevant meetings of ACOG's Practice Committee meetings to further our mutual understanding of FDA's approval for labeling of devices as well as clinical considerations. It was most helpful when Steven Gutman, MD on your staff attended the Committee on Gynecologic Practice meeting in April to discuss the FDA review process for diagnostic devices. It would be most useful to ACOG, and I believe also for the FDA, if a representative from the Obstetric and Gynecologic Devices Branch attends the upcoming meeting of the Committee on Obstetric Practice in October to discuss the pre-marketing approval of HUAM. The Committee on Obstetric Practice meets on October 23 and 24 and we would prefer the FDA representative to attend in the late morning or afternoon of the 23rd. However, we will be glad to accommodate FDA's schedule. The meeting is held at ACOG's office in Washington, DC.

Please let me know at your earliest convenience if Mr. Pollard or another representative will attend the October 23 or 24 meeting of the Committee on Obstetric Practice. For any logistical assistance, please call Debra Hawks, MPH, who staffs that Committee, at (202) 863-2445.

Sincerely yours,

Stanley Zinberg, MD, MS, FACOG
Director of Practice Activities

SZ:lj

cc: Larry Gilstrap, MD, FACOG
Debra Hawks

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