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Dated: November 27, 1996.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96–31229 Filed 12–6–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0463]

Femcare™ Ltd.; Premarket Approval of Filshie Clip System™ (Mark VI)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Family Health International, Research Triangle Park, NC, U.S. Representative for Femcare™ Ltd., Nottingham, U.K., for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Filshie Clip System™ (Mark VI). After reviewing the recommendation of the Obstetrics and Gynecology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 5, 1996, of the approval of the application.

DATES: Petitions for administrative review by January 8, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION: On September 10, 1993, Family Health International, Research Triangle Park, NC, U.S. Representative for Femcare™ Ltd., Nottingham, NG73, England, submitted to CDRH an application for premarket approval of the Filshie Clip System™ (Mark VI). The device is a contraceptive tubal occlusion device (TOD) indicated for permanent female sterilization by occlusion of the fallopian tubes.

On February 26, 1996, the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 5, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 8, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 24, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–31228 Filed 12–6–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0462]

Matritech, Inc.; Premarket Approval of the Matritech NMP22™ Test Kit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Matritech, Inc., Newton, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Matritech NMP22™ Test Kit. After reviewing the recommendation of the Immunology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of July 2, 1996, of the approval of the application.

DATES: Petitions for administrative review by January 8, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food

and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION: On November 7, 1994, Matritech, Inc., Newton, MA 02160, submitted to CDRH an application for premarket approval of the Matritech NMP22™ Test Kit. The Matritech NMP22™ Test Kit is an enzyme immunoassay for the in vitro quantitative determination of nuclear matrix protein NMP22 in stabilized voided urine. The Matritech NMP22™ Test Kit is indicated as an aid in the management of patients with transition cell carcinoma of the urinary tract (TCC/UT), after surgical treatment to identify those patients with occult or rapidly recurring TCC/UT. The Matritech NMP22™ Urine Collection Kit is intended for the collection, stabilization, and transport of human urine which will be tested using the Matritech NMP22™ Test Kit.

On November 30, 1995, the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On July 2, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 8, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: November 7, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–31246 Filed 12–6–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–3070G–I]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Reinstatement without change; *Title of Information Collection:* Intermediate Care Facility for the Mentally Retarded or Persons with Related Conditions Survey Report Form and Supporting Regulations 42 CFR Sections 431, 435, 440, 442 and 483, Subpart I ; *Form No.:* HCFA 3070G–I; *Use:* The survey form and supporting regulations are needed to ensure provider compliance. In order to participate in the Medicaid program as an Intermediate Care Facility for the Mentally Retarded (ICF/MR), providers must meet Federal standards. The survey report form is used to record providers' compliance with the individual standard and report it to the Federal Government. *Frequency:* annually; *Affected Public:* Business or other for-profit, Not for-profit institutions, State, Local or Tribal Govt.; *Number of Respondents:* 7200; *Total Annual Responses:* ,7200; *Total Annual Hours:* 6,074,370.

2. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey Supplement-Round 18; *Form No.:* HCFA–P–15A; *Use:* The Office of the Actuary, HCFA, conducts the Medicare Current Beneficiary Survey (MCBS) through personal interviews of a random sample of Medicare beneficiaries. When sampled persons are found to reside in a long-term care facility, interviewers use a version of the questionnaire which is specially designed to obtain data about the beneficiary's health care from knowledgeable staff members. We are preparing to convert the facility interview from a hardcopy questionnaire to a Computer Assisted Personal Interviewing (CAPI) format beginning in May, 1997. CAPI, which we are currently using in the community interviews, increases the accuracy of the interview process by automating skip patterns, customizing questions, creating computed variables such as a time line of residence history, and automatically checking completeness and consistency of responses. Concurrently, we are modifying some of the questions we currently use in the facility interview to make them more comparable to those in other surveys, particularly the Medical Expenditure Panel Survey (MEPS). These modifications are responsive to the President's initiative toward consistency and integration among surveys; *Frequency:* Annually; *Affected Public:; Number of Respondents:* 1,900; *Total Annual Responses:* 1,900; *Total Annual Hours:* 1,900.