2255 North Dubuque Road, P.O. Box 168, Iowa City, IA 52243 no later than January 23, 1997.

Dated: December 1, 1996.

Louis H. Blair,

Executive Secretary.

[FR Doc. 96–31234 Filed 12–6–96; 8:45 am]

BILLING CODE 6820–AD–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Low Income Home Energy Assistance Program (LIHEAP) Leveraging Report.

OMB No.: 0970–0121.

Description: The report is an annual activity which LIHEAP grantees must submit if they wish to receive a share of leveraging incentive funds that are set aside for this purpose out of annual appropriations. The report provides us with data that allows us to determine whether grantees are carrying out leveraging activities that meet statutory and regulatory requirements for countability. The leveraging incentive funds are awarded based on the amount to countable activities carried out by each grantee, under a formula prescribed by regulation.

Respondents: State governments.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
LIHEAP Leveraging Report	70	1	38	2,660

Estimated Total Annual Burden Hours: 2,660.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: December 3, 1996.

Douglas J. Godesky,

Reports Clearance Officer.

[FR Doc. 96–31141 Filed 12–6–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 88N–0244]

Ear, Nose, and Throat Devices; Denial of Request for Change in Classification of Endolymphatic Shunt Tube With Valve

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying the petition submitted by E. Benson Hood Laboratories, Inc. (Hood Laboratories), to reclassify the endolymphatic shunt tube with valve from class III into class II. The agency is denying the petition because Hood Laboratories failed to provide sufficient new information to establish special controls that would provide reasonable assurance of the safety and effectiveness of the device. This notice also summarizes the basis for the agency's decision. FDA will issue a final rule requiring the filing of premarket approval applications (PMA's) for the device in a future issue of the Federal Register. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), and the Safe Medical Devices Act of 1990 (the SMDA).

EFFECTIVE DATE: March 10, 1997.

FOR FURTHER INFORMATION CONTACT: Harry R. Sauberman, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Classification and Reclassification of Devices under the Medical Device Amendments of 1976

Under section 513 of the act (21 U.S.C. 360c), as amended by the 1976 amendments (Pub. L. 94–295), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA's classification of a device is determined by the amount of regulation necessary to provide reasonable assurance of its safety and effectiveness. Except as provided in section 520(c) of the act (21 U.S.C. 360j(c)), FDA may not use confidential information concerning a device's safety and effectiveness as a basis for reclassification of the device from class III into class II or class I.

Under the 1976 amendments, devices were classified in class I (general controls) if there was information showing that the general controls of the act were sufficient to assure safety and effectiveness; into class II (performance standards) if there was insufficient information showing that general controls would ensure safety and effectiveness, but there was sufficient information to establish a performance standard that would provide such assurance; and into class III (premarket approval) if there was insufficient information to support placing a device into class I or class II and the device was a life-sustaining or life-supporting device or was for a use that is of substantial importance in preventing impairment of human health.

FDA has classified into one of these three regulatory classes most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) under the procedures set forth in section 513(c) and (d) of the act. Under section 513(c) and (d) of the act, FDA secures expert panel recommendations on the appropriate device classifications for generic types of devices. FDA then considers the panel's recommendations and, through notice and comment

rulemaking, promulgates classification regulations.

Devices introduced into interstate commerce for the first time after May 28, 1976, are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Those devices that FDA finds to be substantially equivalent to a classified preamendments generic type of device are thereby classified in the same class as the predicate preamendments device.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based on ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person, and must be based on ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and in 21 CFR 860.7(c)(2). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available in accordance with section 520(c) of the act. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the confidential contents of PMA's.

II. Reclassification under the Safe Medical Devices Act of 1990

The SMDA (Pub. L. 101–629) further amended the act to change the definition of a class II device. Under the SMDA, class II devices are those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance, including the promulgation of a performance standard or other special controls, such as postmarket surveillance, patient registries, guidelines, and other appropriate actions necessary to provide reasonable assurance of the safety and effectiveness of the device. Thus, the definition of a class II device was changed from ''performance standards'' to ''special controls.'' In order for a device that is intended to be implanted in the human body (such as an endolymphatic shunt with valve) to be reclassified from class III into class II, the agency must determine that premarket approval is not necessary to provide reasonable assurance of its safety and effectiveness.

III. Background

In the Federal Register of November 6, 1986 (51 FR 40378), FDA issued a final rule classifying the endolymphatic shunt tube with valve into class III (21 CFR 874.3850). The preamble to the proposal to classify the device included the recommendation of the Ear, Nose, and Throat Devices Panel (the Panel). The Panel's recommendation, among other things, identified certain risks to health (inoperative and clogged valves) presented by the device. In the Federal Register of January 6, 1989 (54 FR 550), FDA published a notice of intent to initiate proceedings to require premarket approval for 31 preamendments class III devices assigned a high priority for the application of premarket approval requirements, including the endolymphatic shunt tube with valve.

In the Federal Register of May 4, 1990 (55 FR 18830), FDA issued a proposed rule under section 515(b) of the act (21 U.S.C. 360e(b)(2)(A)), to require the filing of a PMA or a notice of completion of a product development protocol (PDP) for the endolymphatic shunt tube with valve. The preamble to the proposal included, among other things, the proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the statute's premarket approval requirements and the expected benefit to the public health from the use of the device. The proposal also provided an opportunity for interested persons to request the agency to change the classification of the device based on new information. On July 27, 1990, FDA received a petition (Ref. 1) from the petitioner requesting that the classification of the endolymphatic shunt tube with valve be changed from class III to class II.

IV. Device Description

The endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops of Meniere's disease. The device directs excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption occurs. The function of the pressure-limiting inner ear valve is to maintain the physiologically normal endolymphatic pressure and to assure a unidirectional flow of endolymph.

Hood Laboratories' endolymphatic shunt tube with valve is the only device of its type in commercial distribution legally in the United States. It consists of a Supramid™ catheter tube connected to a silicone tube that is inside a silicone molded body. The inside silicone tube has a slit valve at one end that allows the endolymph to exit. The Supramid™ tube is inserted into the end of the endolymphatic sac so that the endolymph will flow through the valve and into the mastoid cavity via the tail-like portion of the molded silicone body.

V. Recommendation of the Panel

In a public meeting held on June 11, 1992, the Panel met to discuss the reclassification petition submitted by Hood Laboratories. The Panel noted the similarities between the valved and nonvalved shunts. Both the valved shunt device (class III) and the nonvalved shunt device (class II) drain excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption occurs. Both devices are intended to relieve the symptoms of Meniere's disease. The nonvalved shunt (class II device) permits the unrestricted flow of excess endolymph, while the valved shunt (class III device) is intended to control the flow of endolymph so that a normal endolymphatic pressure is maintained.

The Panel acknowledged the difficulty in diagnosing, treating, and assessing the treatment plans for Meniere's disease and could not agree that the valved shunt is effective, but believed the device ''does something worthwhile'' in treating the symptoms. They also noted the lack of objective scientific data establishing that the device operates as a one-way valve to regulate the endolymphatic pressure. While acknowledging that the petitioner had not presented sufficient information to establish special controls to provide reasonable assurance of safety and effectiveness of the devices, three of the five voting members recommended reclassifying the generic endolymphatic shunt with valve from class III into class II.

VI. Agency Decision

Based on its review of the information contained in the petition and presented at the panel meeting, as well as the Panel's discussion, the agency respectfully disagrees with the Panel's recommendation. FDA finds that the petition contains insufficient valid scientific evidence to determine that special controls, in addition to the general controls applicable to all devices, would provide reasonable assurance of the device's safety and

effectiveness for its intended use. FDA, therefore, is denying the petition.

VII. Reasons for the Denial

FDA has determined that Hood Laboratories has not presented sufficient new scientific information to support the requested change in classification of this device. FDA has further determined that Hood Laboratories did not adequately address the issues of normal endolymphatic sac pressure, the mode of action of the endolymphatic shunt tube with valve, flow characteristics, nor the risks associated with the use of the device. The endolymphatic shunt tube with valve is intended to relieve the symptoms of Meniere's disease by employing a unidirectional valve, which reportedly opens at 10 millimeters of mercury (mm Hg) pressure to maintain the normal physiological pressure of the endolymphatic system. The lack of information addressing the issues of normal physiological pressure within the endolymphatic system, as noted in the preamble to the final rule classifying the device (51 FR 40378 at 40385), remains a concern. FDA believes that objective scientific data, including clinical studies, are necessary to establish that the device is effective for its intended purpose. FDA also believes that clinical and nonclinical data are necessary to define the full range of physiological pressures present within the endolymphatic system and to define the flow characteristics attributable to the device and to the valve component. These issues remain unresolved. The agency further believes that an alternative treatment exists for the relief of Meniere's disease.

Current literature suggests that the natural flow of endolymph is very slow and that the pressure increases associated with endolymphatic hydrops may not be large in magnitude. Because current technology does not exist to allow the measurement of endolymph flow rates or endolymphatic pressure in humans, the animal studies discussed below provide the only information available to determine if the valve functions to maintain normal endolymphatic pressure. In the first study, Long and Morizono employed a micropressure system to measure the hydrostatic pressure of endolymph and perilymph in a guinea pig model of endolymphatic hydrops (Ref. 2). The authors reported the magnitude of the pressure difference between perilymph and endolymph that could be attributed to endolymphatic hydrops to be less than 0.5 mm Hg (within 95 percent confidence limits). In another study, Salt and Thalmann reported the average flow rate (velocity) of endolymph in the basal turn of the guinea pig cochlea to be 0.005 mm per minute using ionic tracers measured by ion-selective electrodes (Ref. 3).

Alec N. Salt, an invited guest speaker at the June 11, 1992, Panel meeting, concluded that the reported low flow rate of endolymph demonstrated that endolymph flow is not a significant homeostatic mechanism in the inner ear. He noted that, based on measurements of calcium ion levels within the cochlea of guinea pigs, the induction of endolymphatic hydrops elevated endolymph calcium ion concentration by an amount likely to impair hair cell function. Alec N. Salt concluded that these data suggest that an elevated calcium ion level may have a major role in the development of hearing impairment associated with endolymphatic hydrops in guinea pigs (Ref. 4). In a study of the long-term effects of destruction of the endolymphatic sac in a primate species (monkeys), none of the animals developed severe endolymphatic hydrops or the cochleo-vestibular symptoms that occur in human subjects with Meniere's disease (Ref. 5).

The animal studies cited above do not support an increase in endolymphatic pressure as the sole mechanism inducing the clinical findings observed in humans. The claim of maintenance of normal endolymphatic pressure by means of the endolymphatic shunt tube with valve has not been established despite numerous nonclinical and clinical studies involving the use of this device over the last 15 years. FDA believes that the mode of operation of the valved shunt is not supported by valid scientific evidence and remains to be established.

FDA notes that the benefits resulting from implantation of the endolymphatic shunt tube with valve, i.e., relief of vertigo, fluctuating hearing loss, tinnitus, and aural fullness, which typify Meniere's disease, appear to be very similar to those resulting from implantation of nonvalved shunts (Refs. 6, 7, and 8). Huang and Lin reported that risks such as the incidence of infections, iatrogenic deaf ears, and clogging have a similar occurrence in valved and nonvalved endolymphatic shunts (Ref. 6). However, the risk concerns raised in the proposed rule about any build up of fluid pressure in the inner ear because of a clogged or inoperative valved device or about the risk of infection from revision surgery were not addressed by Hood Laboratories and remain unanswered (55 FR 18830).

During the June 11 panel meeting, the Panel questioned whether the valve component of the shunt tube actually functions as a pressure-regulating valve. Questions regarding the true range of physiological pressures that one may expect to find within the endolymphatic sac, as well as the flow characteristics that one would find attributable to an effective functioning of the valve remain unanswered. In its deliberations, the Panel determined that Hood Laboratories had not presented sufficient valid scientific evidence as to whether the valve actually functions as a valve in vivo.

Another invited guest speaker, Douglas E. Mattox, reviewed the histology and ultrastructure of four failed, explanted valved shunts. Using scanning electron microscopy, multiple erosions along the length of the Supramid™ tube and liner and irregular erosion of the tip (Ref. 9) were shown. This finding calls into question the long-term functioning and integrity of the endolymphatic shunt tube with valve as currently marketed by Hood Laboratories.

Despite the potential benefits of the device in improving hearing, relief of vertigo, reduction of the fullness in the ear, and mitigation of tinnitus, FDA believes that little new information is available about the physiological functions and mode of operation of the device and therefore, the device presents serious potential risks. FDA believes that the petition lacks sufficient valid scientific evidence to determine that special controls would provide reasonable assurance of the safety and effectiveness of the endolymphatic shunt tube with valve for its intended use. Therefore, the endolymphatic shunt tube with valve shall be retained in class III (premarket approval). In a future issue of the Federal Register, FDA will promulgate a final rule under section 515(b) of the act to require the filing of a PMA by each manufacturer of this device.

VII. References

The following information has been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. E. Benson Hood Laboratories, Inc., Reclassification Petition, Docket No. 88N–0244.

2. Long, C. H., and T. Morizono, ''Hydrostatic Pressure Measurement of Endolymph and Perilymph in a Guinea Pig Model of Endolymphatic Hydrops,'' *Otolaryngology Head and Neck Surgery*, 96:83–95, 1987.

3. Salt, A. N., and R. Thalmann (Review Chapter), ''Cochlear Fluid Dynamics,'' *Physiology of the Ear*, edited by A. F. Jahn, and J. R. Santos-Sacchi, Raven Press, New York, pp. 341–357, 1988.

4. Salt, A. N., and J. E. DeMott, ''Endolymph Calcium Increases with Time in Hydropic Guinea-Pigs,'' *Abstracts of the Fifteen Midwinter Research Meeting*, Association for Research in Otolaryngology, p. 128, 1992.

5. Swart, J. G., and H. F. Schuknect, ''Long-Term Effects of Destruction of the Endolymphatic Sac in a Primate Species,'' *Laryngoscope*, 98:1183–1189, 1988.

6. Huang, T. S., and C. C. Lin, ''Endolymphatic Sac Surgery for Meniere's Disease: A Composite Study of 339 Cases,'' *Laryngoscope*, 95:1082–1086, 1985.

7. Huang, T. S., ''Valve Implants Compared to Other Surgical Methods,'' *American Journal of Otology*, 8:301–305, 1987.

8. Wright, J. W., and G. W. Hicks, ''Valved Implants in Endolymphatic Surgery,'' *American Journal of Otology*, 8:307–312, 1987.

9. Cohen, E. J., and D. E. Mattox, ''Histology and Ultrastructure of Explanted Arenberg Shunts,'' Presented at the Annual Meeting of the American Otologic Society, Palm Desert, CA, April 12–13, 1992.

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