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