

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) Household Report.

OMB No.: 0970-0060.

Description: The report is an annual activity which is required by law of LIHEAP grantees for receipt of federal LIHEAP block grant funds. Statistics are to be reported for the previous federal fiscal year on the number and income levels of LIHEAP applicants and assisted households, and the number of LIHEAP assisted households with at least one member who is elderly,

disabled, or a young child. The information is being collected for the Department's annual LIHEAP report to Congress and is used to provide information about the need for and use of LIHEAP funds. The information may also be used as performance measures under the Government Performance Results Act of 1993.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|-----------------------|------------------------------------|-----------------------------------|--------------------|
| LIHEAP Assisted Long Form | 52 | 1 | 25 | 1,300 |
| LIHEAP Assisted Short Form | 131 | 1 | 1 | 131 |
| LIHEAP Application Household Report | 52 | 1 | 13 | 676 |

Estimated Total Annual Burden Hours: 2,107.

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: April 11, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97-9823 Filed 4-15-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. 93631-97-01]

Developmental Disabilities: Request for Public Comments on Proposed Developmental Disabilities Funding Priorities for Projects of National Significance for Fiscal Year 1997

AGENCY: Administration on Developmental Disabilities (ADD), Administration for Children and Families (ACF).

ACTION: Notice of request for public comments on developmental disabilities tentative funding priority for Projects of National Significance for Fiscal Year 1997.

SUMMARY: The Administration on Developmental Disabilities, Administration for Children and Families, announced that public comments are being requested on tentative funding priorities for Fiscal Year 1997 Projects of National Significance prior to being announced in its final form.

We welcome specific comments and suggestions on this proposed announcement and funding priority which will assist in bringing about the increased independence, productivity, integration, and inclusion into the community of individuals with developmental disabilities.

DATES: The closing date for submission of public comments is June 16, 1997.

ADDRESSES: Comments should be sent to: Bob Williams, Commissioner, Administration on Developmental

Disabilities, Administration for Children and Families, Department of Health and Human Services, Room 329-D, HHH Building, 200 Independence Avenue, S.W., Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: Adele Gorelick, Program Development Division, Administration on Developmental Disabilities, 202/690-5982.

SUPPLEMENTARY INFORMATION:

Part I

Background

A. Goals of the Administration on Developmental Disabilities

The Administration on Developmental Disabilities is located within the Administration for Children and Families, Department of Health and Human Services (DHHS). Although different from the other ACF program administrations in the specific constituency it serves, ADD shares a common set of goals that promote the economic and social well-being of families, children, individuals and communities. Through national leadership, we see:

- Families and individuals empowered to increase their own economic independence and productivity;
- Strong, healthy, supportive communities having a positive impact on the quality of life and the development of children;
- Partnerships with individuals, front-line service providers, communities, States and Congress that enable solutions which transcend traditional agency boundaries;
- Services planned and integrated to improve client access; and

- A strong commitment to working with Native Americans, individuals with developmental disabilities, refugees and migrants to address their needs, strengths and abilities.

Emphasis on these goals and progress toward them will help more individuals, including those with developmental disabilities, to live productive and independent lives integrated into their communities. The Projects of National Significance Program is one means through which ADD promotes the achievement of these goals.

Two issues are of particular concern with these projects. First, there is a pressing need for networking and cooperation among specialized and categorical programs, particularly at the service delivery level, to ensure continuation of coordinated services to people with developmental disabilities. Second, project findings and successful innovative models of projects need to be made available nationally to policy makers as well as to direct service providers.

B. Purpose of the Administration on Developmental Disabilities

The Administration on Developmental Disabilities is the lead agency within ACF and DHHS responsible for planning and administering programs which promote the self-sufficiency and protect the rights of individuals with developmental disabilities.

The Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6000 *et seq.*) (the Act), as amended provides assistance to States and public and private nonprofit agencies and organizations to assure that individuals with developmental disabilities and their families participate in designing, and have access to, culturally competent services, supports and other assistance and opportunities that promote independence, productivity and integration and inclusion into the community.

The Act points out that:

- Disability is a natural part of the human experience that does not diminish the right of individuals with developmental disabilities to enjoy the opportunity for independence, productivity and inclusion into the community;
- Individuals whose disabilities occur during their developmental period frequently have severe disabilities that are likely to continue indefinitely;
- Individuals with developmental disabilities often require lifelong specialized services and assistance, provided in a coordinated and culturally competent manner by many

agencies, professionals, advocates, community representatives, and others to eliminate barriers and to meet the needs of such individuals and their families;

The Act further finds that:

- Individuals with developmental disabilities, including those with the most severe developmental disabilities, are capable of achieving independence, productivity, and integration and inclusion into the community, and often require the provision of services, supports and other assistance to achieve such;
- Individuals with developmental disabilities have competencies, capabilities and personal goals that should be recognized, supported, and encouraged, and any assistance to such individuals should be provided in an individualized manner, consistent with the unique strengths, resources, priorities, concerns, abilities and capabilities of the individual;
- Individuals with developmental disabilities and their families are the primary decision makers regarding the services and supports such individuals and their families receive and play decision-making roles in policies and programs that affect the lives of such individuals and their families; and
- It is in the nation's interest for individuals with developmental disabilities to be employed, and to live conventional and independent lives in families and communities.

Toward these ends, ADD seeks: to enhance the capabilities of families in assisting individuals with developmental disabilities to achieve their maximum potential; to support the increasing ability of individuals with developmental disabilities to exercise greater choice and self-determination and to engage in leadership activities in their communities; and to ensure the protection of legal and human rights of persons with developmental disabilities.

Programs funded under the Act are:

- Federal assistance to State developmental disabilities councils;
- State system for the protection and advocacy of individual rights;
- Grants to university affiliated programs for interdisciplinary training, community services, technical assistance, and information dissemination; and
- Grants for Projects of National Significance.
 - Technical assistance to enhance the quality of State development disabilities councils, protection and advocacy systems, and university affiliated programs; and
 - Other projects of sufficient size and scope that hold promise to expand or

improve opportunities for individuals with developmental disabilities, including:

- technical assistance for developing information and referral systems;
- educating policy makers;
- Federal interagency initiatives;
- enhancing participation of racial and ethnic minorities in public and private sector initiatives in developmental disabilities;
- transition of youth with developmental disabilities from school to adult life; and
- special pilots and evaluation studies to explore the expansion of programs under part B (State developmental disabilities councils) to individuals with severe disabilities other than developmental disabilities.

Section 162(d) of the Act requires that ADD publish in the **Federal Register** proposed priorities for grants and contracts to carry out Projects of National Significance. The Act also requires a 60-day period for public comment on proposed priorities. After analyzing and considering such comments, ADD must publish in the **Federal Register** final priorities and solicit applications for funding based on the final priorities selected.

The following section presents the proposed priority areas for Fiscal Year 1997 Projects of National Significance. We welcome specific comments and suggestions. We would also like to receive suggestions on timely topics related to specific needs in the development disabilities field.

Please be aware that the development of the final funding priority is based on the public comment response to this notice, current agency and Departmental priorities, needs in the field of developmental disabilities and the developmental disabilities network, etc., and the availability of funds for this fiscal year.

Part II

Fiscal Year 1997 Proposed Priority Areas for Projects of National Significance

ADD is interested in all comments and recommendations which address areas of existing or evolving national significance related to the field of developmental disabilities.

ADD also solicits recommendations for project activities which will advocate for public policy change and community acceptance of all individuals with developmental disabilities and families so that such individuals receive the culturally competent services, supports, and other

assistance and opportunities necessary to enable them to achieve their maximum potential through increased independence, productivity, and integration into the community.

ADD is also interested in activities which promote the inclusion of all individuals with developmental disabilities, including individuals with the most severe disabilities, in community life; which promote the interdependent activity of all individuals with developmental disabilities and individuals who are not disabled; and which recognize the contributions of these individuals (whether they have a disability or not), as such individuals share their talents at home, school, and work, and in recreation and leisure time.

No proposals, concept papers or other forms of applications should be submitted at this time. Any such submission will be discarded.

ADD will not respond to individual comment letters. However, all comments will be considered in preparing the final funding solicitation announcement and will be acknowledged and addressed in that announcement.

Please be reminded that, because of possible funding limitations, the proposed priority areas listed below may not be published in a final funding solicitation for this fiscal year.

Comments should be addressed to: Bob Williams, Commissioner, Administration on Developmental Disabilities, Department of Health and Human Services, Room 329-D HHH Building, 200 Independence Avenue, S.W., Washington, D.C. 20201.

Proposed Fiscal Year 1997 Priority Area 1: Managed Care and Disability

The delivery systems and financing through which health care is provided to the nation's population have undergone monumental changes over the past three decades. For the majority of its history, the health care system in the United States has utilized a fee-for-service model; services are provided and then the bill is paid based on what was done (retrospective payment system). We are now moving toward a prospective or prepayment based approach where a provider is paid a set fee based on the number of patients to be served and services are rendered only as needed. This system is synonymous with managed care which promises to control costs and improve access to a coordinated continuum of services. To the public and private sectors it presents a solution to uncontrollable expenditures. For children and adults with developmental disabilities and

their families, the trend towards managed care presents a mix of risks, challenges and opportunities.

If the managed care system of health delivery is to meet the expectations of the public and private sectors and provide appropriate quality acute health care and long-term services to people with developmental disabilities and their families, a number of challenges and fundamental questions must be addressed:

- How can community long-term services and supports that are consumer responsive and non-medical be integrated in acute health care under a managed care plan?

How can managed care avoid imposing a medical model of care that is inconsistent with extensive, inclusive, consumer responsive, community long-term services and supports?

- How will the core values of disability policy (non-discrimination, inclusion/participation, consumer choice) be incorporated into managed care if it is to provide quality, appropriate acute and long-term services and supports?

- How can States and others best ensure the meaningful involvement of people with developmental disabilities and their families throughout the process of designing and planning a managed care system?

- What are the elements of a managed care system that is cost-effective, outcomes-oriented, and consumer-sensitive to the segment of the population with developmental disabilities?

- What is "state-of-the-art managed care" for this special health care group?

- How do we ensure the practices under managed care (i.e., gatekeepers, restrictive definitions of medical necessity, biased utilization review criteria) when applied to individuals with developmental disabilities who may need more, or different, health care services to maintain their health and function effectively is non-discriminatory?

To support our goal of independence, productivity, and integration, ADD is interested in ideas to empower individuals with developmental disabilities and their families to take a leadership role in their States on managed care, welfare reform, and other emerging concerns. This could be accomplished through a national center to provide technical assistance in leadership development to enable the people most affected to be effective players in their communities and States. This center should be directed from a consumer perspective yet represent a

consortium of the developmental disabilities network, independent living, self-advocates, parents, and organizations representing minority communities. This consortium should be replicated at the State level in a collaboration to develop and implement strategies to foster/facilitate disability and parent leadership in managed care, welfare reform, and other significant areas.

Leadership development requires not only skills but knowledge. This center must acquire state-of-the-art general and technical information and numerous aspects and issues that individuals with developmental disabilities and parents of children with developmental disabilities will need to participate in State-level activities and processes. It will be necessary to have a resource pool of consultants that can be utilized as needed.

PNS projects on leadership development and individuals of color with developmental disabilities, cultural competency of the DD network, and personal assistance service have developed training materials, curricula, strategies, linkages, legislative proposals, policies, and more. The center should build upon these projects.

This is one idea that ADD has concerning this topic but it is also interested in any proposed priorities and approaches addressing this area.

Proposed Fiscal Year 1997 Priority Area 2: Technical Assistance and Knowledge Transfer on Welfare Reform and Individuals with Developmental Disabilities and their Families

Over a million children and adults with disabilities and their families will be directly affected by the implementation of all aspects of the Personal Responsibility and Work Opportunity Reconciliation Act. Such individuals and families should have an equal opportunity to realize the full promise of Welfare Reform, including the chance to work their way out of poverty, while keeping their families health, safe and intact.

Significant research, best practices and lessons learned exist in regard to assisting children and adults with the full range of disabilities to live, work and become contributing members of their families, communities and nation. States, communities, businesses, disability constituencies and others can benefit from technical assistance aimed at assisting them to transfer, adapt and apply such knowledge and practice to Welfare Reform activities.

Such technical assistance should seek to better equip these major stakeholders with the skills, knowledge and expertise

necessary to apply what is already known to work for persons with developmental disabilities and their families to the Welfare Reform context in respect to:

- (1) Assuring the basic civil rights of, and equal opportunity for, individuals with developmental disabilities and their families on the Temporary Assistance for Needy Families (TANF) Program;
- (2) Making work pay for low-income parents with developmental disabilities and parents of children with developmental disabilities on TANF;
- (3) Encouraging job/business creation by and for low-income families and individuals with developmental disabilities;
- (4) Increasing the access and responsiveness of Head Start and Child Care Programs to families of children with developmental disabilities and parents with developmental disabilities;
- (5) Supporting and strengthening poor families experiencing developmental disabilities;
- (6) Promoting the healthy and safe development of children with developmental disabilities and their families;
- (7) Making welfare reform work for teen parents and other at-risk young people with developmental disabilities;
- (8) Making tribal welfare reform work for Native Americans with developmental disabilities and their families;
- (9) Making welfare reform work for refugees and legal immigrants with developmental disabilities and their families; and
- (10) Enhancing child support enforcement.

ADD proposes to fund a national technical assistance and knowledge transfer center on effective Welfare Reform for people with developmental disabilities and their families. The mission of such a center would be to work with States, the disability community, businesses and others to enhance the likelihood that adults and children with developmental disabilities as well as their families on TANF would have an opportunity to benefit from all aspects of Welfare Reform. Specifically, the center would work with all relevant stakeholders to:

- Track and report on trends and practices in welfare reform affecting children and adults with developmental disabilities;
- Convene working conferences to develop and share strategies for responding to opportunities and risks in Welfare Reform for such individuals and families;

- Conduct, sponsor, assist in and disseminate relevant research findings pertaining to: (i) the effects of Welfare Reform on persons with developmental disabilities and their families; and, (ii) relationships between disability, poverty, gender, ethnicity and dependency on Aid to Families with Dependent Children (AFDC) and TANF;

- Function as a clearinghouse on all relevant information, emerging knowledge, policy, best practices and research;
- Broker technical assistance, especially peer-to-peer consultations, designed to assist such stakeholders to work together to apply to Welfare Reform research and best practices regarding what works for persons with developmental disabilities and their families;
- Assist researchers conducting large-scale evaluations of Welfare Reform to assure that such studies are designed and carried out with sensitivity to a wide range of disability policy concerns;
- Track, synthesize, disseminate, facilitate the adaptation and/or replication of best or promising approaches, as well as lessons learned, especially those supported by investments of ADD in DD Councils, Protection and Advocacy Systems, University Affiliated Programs, Projects of National Significance and other Federal or State agencies or foundations;
- Expand leadership development opportunities among individuals and families experiencing developmental disabilities in economically disadvantaged communities; and,
- Sponsor forums, on-line conferences and other ongoing exchanges to facilitate a greater understanding of the impacts of Welfare Reform on individuals with developmental disabilities and their families on the part of States, the disability community, foundations, researchers and others.

Proposed Fiscal Year 1997 Priority Area 3: Technical Assistance and Knowledge Transfer on Self-Determination and Responsible Leadership by and for Individuals with Developmental Disabilities and Families of Children with Developmental Disabilities

All Americans, including people with developmental and other disabilities, should experience opportunities and a sense of community and responsibility in their lives. In fact, one of the central tasks facing us is to devise ways we as individuals, families, communities and a nation can actively promote the responsibility people with disabilities have for their own and our collective lives and futures. Federal legislation

such as the Developmental Disabilities Act, the Individuals with Disabilities Education Act and the Americans with Disabilities Act are all grounded in the fundamental principle that persons with disabilities and their families have a critical need, and as a matter of right ought, to be primary decision-makers in any decision affecting their lives and futures.

The majority of the progress we have made as a society in this regard in the past quarter century has shown us that responsible leadership for and by people with developmental and other disabilities and their families is a prerequisite to increasing independence, productivity, integration and inclusion of such individuals and their families. ADD and individual DD Councils, Protection and Advocacy Systems and University Affiliated Programs have found that developing, nurturing and sustaining strategic, creative and responsible leadership on the part of individuals with developmental and other disabilities and their families have been among the most high-yielding long-term investments made.

Through Projects of National Significance, in particular, ADD has assisted its grantees to develop and replicate a variety of innovative, successful approaches to develop leadership and self-determination among people with developmental disabilities and their families. Most notably, this has taken the form of early and formative support of such endeavors as Partners in Policy, the active participation of families of children with developmental disabilities in designing and implementing of State family support policies and programs, the Home of Your Own initiative, personal assistance system change projects, and targeted leadership efforts among people of color with developmental disabilities.

Now more than ever, the States, the disability community and others require support and assistance in strategically working through the cumulative effects Welfare Reform, SSI changes, managed care and Medicaid restructuring might have on adults and children with developmental disabilities as well as their families. Responsible leadership by people with developmental and other disabilities and their families, is value driven and recognizes the new and emerging realities facing State and local governments today. Such leadership is critical to finding responsible and cost effective ways to strengthen the abilities and opportunities of individuals with developmental disabilities and families of children with developmental

disabilities to exercise choice and self-determination throughout their daily lives. This is true in respect to most people with developmental disabilities and families of children with developmental disabilities, but is particularly the case in regard to those living in poverty.

To address this set of challenges and opportunities, ADD proposes to fund a national technical assistance and knowledge transfer center on self-determination and 21st Century leadership development. The mission of such a center would be to work with all relevant stakeholders to expand and sustain responsible leadership by and for people with developmental disabilities and families of children with developmental disabilities in shaping and guiding the implementation of policies, practices and approaches which enhance their own self-determination and self-efficacy.

Specifically, the center would seek to strengthen and expand leadership for the 21st Century by and for people with developmental disabilities and families of children with developmental disabilities through:

- Building, expanding and strengthening what works in this regard.
- Brokering technical assistance, especially peer-to-peer consultations, designed to assist such stakeholders to work together to apply research and best practices to enhance the self-determination and self-efficacy of persons with developmental disabilities and families of children with developmental disabilities (especially in States and communities that have not taken part in similar initiatives relating to Partners in Policy, family support, home ownership, personal assistance, self-determination, etc.).
- Expanding self-determination opportunities and roles for young people with and without developmental disabilities (ages 12–25) as well as individuals with significant developmental disabilities and families of children with developmental disabilities from economically disadvantaged communities.
- Convening working conferences to develop and share strategies for enhancing self-determination in the context of the changing roles of the State and Federal Governments, governmental reinvention activities, a heightened focus on achieving results and cost effectiveness, welfare reform, changes in SSI, managed care and proposals for Medicaid restructuring.
- Conducting, sponsoring, assisting in and disseminating relevant research findings pertaining to the prospects for

enhancing self-determination and influencing policy in the changing Federal and State context described above.

- Functioning as a clearinghouse on all relevant information, emerging knowledge, policy, best practices and research.
- Tracking, synthesizing, disseminating, facilitating the adaptation and/or replication of best or promising approaches, and lessons learned, especially those supported by investments of ADD in DD Councils, Protection and Advocacy Systems University Affiliated Programs, Projects of National Significance and other Federal or State agencies or foundations.
- Sponsoring forums, on-line conferences and other ongoing exchanges to facilitate a greater understanding of the impacts of welfare reform on individuals with developmental disabilities and their families on the part of States, the disability community, foundations, researchers and others.

Proposed Fiscal Year 1997 Priority Area 4: The National Center for the Analysis of Major Trends and Outcomes Data Regarding Individuals with Developmental Disabilities and Their Families

ADD together with Developmental Disabilities Councils, Protection and Advocacy Systems, University Affiliated Programs and Projects of National Significance are responsible for helping to bring about the increased independence, productivity, integration and inclusion of all individuals with developmental disabilities in every aspect of American life. In enacting Federal legislation such as the Developmental Disabilities Act, the Individuals with Disabilities Education Act and the Americans with Disabilities Act, the Congress also has found that persons with disabilities and their families have a critical need and as a matter of right should be primary decision-makers in any decision affecting their lives and futures. ADD and its grantees, therefore, have significant roles in strengthening the capabilities and expanding the opportunities of individuals with developmental disabilities and families of children with developmental disabilities to exercise choice and self-determination throughout their daily lives. It is critical to recognize that a variety of other broad governmental, economic and social forces influence much more directly the achievement of these vital national aims.

Accurately measuring, tracking and reporting on the extent to which our

society is progressing toward these goals is crucial to assessing both the overall effectiveness of the ADD programs and that of the Nation as a whole in carrying on this endeavor.

ADD has supported a number of initiatives particularly through PNS, and ongoing projects designed to strengthen, expand and sustain our collective understanding of the changing status of Americans with developmental disabilities. This has taken the form of both the formative and ongoing support for such endeavors as:

- The three national data collection and dissemination projects;
- The development of the ADD Management Information System;
- The Data Trends Conference cosponsored with NIDRR;
- The AAUAP data collection project; and
- The disability supplement to the National Health Interview Survey.

To build on these and other efforts and to further foster the pursuit of excellence through its leadership and that of its programs, ADD proposes to fund a National Center for the Analysis of Major Trends and Outcomes Data Regarding Individuals with Developmental Disabilities and Their Families. The mission of such a center would be to work with all relevant stakeholders around a number of tasks that could include the following:

- (1) Build and expand upon all current and past efforts undertaken by ADD and all others in this area;
- (2) Identify, synthesize, and report on major data sources on major trends affecting the lives, well being and futures of all Americans, including those with developmental and other disabilities as well as their families;
- (3) Identify, synthesize, and report on major data sources on major trends specific to the lives, well-being and futures of individuals with developmental disabilities and their prospects for their increased independence, productivity, integration and inclusion and greater choice and self-determination throughout their everyday lives;
- (4) Develop, continually improve, and work with ADD, its programs and all other relevant Federal, State and private entities to infuse outcome measures and other indicators accurately reflecting the status of persons with developmental disabilities and the families of children with developmental disabilities into major surveys and studies;
- (5) Develop in close consultation and collaboration with individuals with developmental disabilities and families of children with developmental disabilities a prototypical survey

instrument to assess the extent to which such individuals and families believe they have opportunities to exercise meaningful choice and self-determination and to carry out personal responsibilities in life; and

(6) Develop a prototypical public opinion survey instrument which can be reliably and cost effectively administered to a representative national sample of the general public at least once every five years.

(Federal Catalog of Domestic Assistance Number 93.631—Developmental Disabilities—Projects of National Significance)

Dated: April 10, 1997.

Bob Williams,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 97-9801 Filed 4-15-97; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0139]

Genzyme Corp.; Premarket Approval of Septrafilm™ Bioresorbable Membrane

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Genzyme Corp., Cambridge, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Septrafilm™ Bioresorbable Membrane. After reviewing the recommendation of the General and Plastic Surgery Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 12, 1996, of the approval of the application.

DATES: Petitions for administrative review by May 16, 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: Stephen P. Rhodes, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090.

SUPPLEMENTARY INFORMATION: On October 27, 1995, Genzyme Corp.,

Cambridge, MA 02139-1562, submitted to CDRH an application for premarket approval of Septrafilm™ Bioresorbable Membrane. The device is an absorbable adhesion barrier and is indicated for use in patients undergoing abdominal or pelvic laparotomy as an adjunct intended to reduce the incidence, extent, and severity of postoperative adhesions between the abdominal wall and the underlying viscera such as omentum, small bowel, bladder, and stomach, and between the uterus and surrounding structures such as tubes and ovaries, large bowel and bladder.

On March 25, 1996, the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On August 12, 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 May 15, 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: March 17, 1997.

Joseph A. Levitt,

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

[FR Doc. 97-9726 Filed 4-15-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-2552, HCFA-R-88]

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:* Extension of a currently approved collection; *Title of Information Collection:* Hospital and Hospital Health Care Complex Cost Report, 42 CFR 413.20 and 413.24; *Form No.:* HCFA-2552-96; *Use:* This form is