

with applicable supporting documentation, maybe obtained by calling the Administration for Children and Families, Reports Clearance Officer, Bob Sargis at (202) 690-7275.

Comments and questions about the information collection described above should be directed to the following address by April 30, 1999: Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paper Reduction Project, 725 17th Street, NW, Washington, DC 20503, (202) 395-7316.

Dated: April 14, 1999.

**Bob Sargis,**

*Reports Clearance Officer.*

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BILLING CODE 4184-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[Program Announcement No. 93631-99-02]

#### Developmental Disabilities: Request for Public Comments on Proposed Developmental Disabilities Funding Priorities for Projects of National Significance for Fiscal Year 1999

**AGENCY:** Administration on Developmental Disabilities (ADD), ACF, DHHS.

**ACTION:** Notice of request for public comments on developmental disabilities tentative funding priorities for Projects of National Significance for Fiscal Year 1999.

**SUMMARY:** The Administration on Developmental Disabilities (ADD) announced that public comments are being requested on tentative funding priorities for Fiscal Year 1999 Projects of National Significance prior to being announced in its final form.

We welcome comments and suggestions on this proposed announcement and funding priorities that 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 applications is June 21, 1999.

**ADDRESSES:** Comments should be sent to: Sue Swenson, Commissioner, Administration on Developmental Disabilities, Administration for Children and Families, Department of Health and Human Services, 370 L'Enfant Promenade, S.W., Room 300F, Washington, D.C., 20447.

**FOR FURTHER INFORMATION CONTACT:** Administration for Children and Families (ACF), Pat Laird, 370 L'Enfant Promenade, S.W., Room 300F, Washington, D.C., 20447, 202/690-7447.

**SUPPLEMENTARY INFORMATION:** This announcement consists of two parts:

#### 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 that promote the self-sufficiency and protect the rights of individuals with developmental disabilities.

The 1996 Amendments (Public Law 104-183) to the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C.6000 *et seq.*) (the Act) supports and provides assistance to States and public and private nonprofit agencies and organizations to assure that individuals with developmental disabilities and their families participate in the design of 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 as a part of 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, to engage in leadership activities in their communities, as well as to ensure the protection of their legal and human rights.

Programs funded under the Act are:

- Federal assistance to State developmental disabilities councils;
- State system for the protection and advocacy of individual's rights;
- Grants to university affiliated programs for interdisciplinary training, exemplary services, technical assistance, and information dissemination; and
- Grants for Projects of National Significance.

### C. Description of Projects of National Significance

Under Part E of the Act, demonstration grants and contracts are awarded for projects of national significance that support the development of national and State policy to enhance the independence, productivity, and integration and inclusion of individuals with developmental disabilities through:

- Data collection and analysis;
- Technical assistance to enhance the quality of State developmental 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 the development of information and referral systems;
- Educating policy makers;
- Federal interagency initiatives;
- The enhancement of 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.

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 period of 60 days for public comment concerning such proposed priorities. After analyzing and considering such comments, ADD must publish in the **Federal Register** final priorities for such grants and contracts, and solicit applications for funding based on the final priorities selected.

The following section presents the proposed priority areas for Fiscal Year 1999 Projects of National Significance. We welcome specific comments and suggestions. We would also like to receive suggestions on topics which are timely and relate to specific needs in the developmental 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., as well as the availability of funds for this fiscal year.

### Part II

#### *Fiscal Year 1999 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 people with developmental disabilities and people without disabilities; and which recognize the contributions of these people (whether they have a disability or not), who 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: Sue Swenson, Commissioner, Administration on Developmental Disabilities, Administration for Children and Families, Department of Health and Human Services, 370 L'Enfant Promenade, S.W., Room 300F, Washington, D.C. 20447.

#### *Proposed Fiscal Year 1999 Priority Area 1: Ongoing Data Collection and Information Dissemination*

The purpose of this priority area is to fund projects through a cooperative agreement to collect data on public expenditures, employment and economic status, residential services, and other factors as they impact on the independence, productivity, integration and inclusion into the community of persons with developmental disabilities. ADD is particularly interested in the maximum use of already existing databases and in fostering the broadest dissemination to and use of the data by consumers, families and advocacy audiences.

Recently both public and private organizations have focused on data regarding people with disabilities. In 1998 the National Organization on Disability sponsored a Louis Harris survey on employment of adults with disabilities in the United States to determine whether their quality of life had improved since the passage of the Americans with Disabilities Act (ADA). In 1994 and 1995 a Disability Supplement was included in the National Health Interview Survey (NHIS). The NHIS is a household survey that has been conducted by the U.S. Bureau of the Census annually since 1957 and is supported by the National Center for Health Statistics. The NHIS focuses on the civilian, non-institutionalized population in the United States. Each year the NHIS randomly samples approximately 46,000 households with 116,000 members. The Disability Supplement

was included in this survey to identify a range of items necessary for gathering baseline data on disability, including developmental disabilities in this country. Other organizations are attempting to develop usable data on particular aspects of the lives of people with disabilities as well as include disability as a demographic factor in general surveys.

In December 1998 the ADD hosted a roundtable on data. This was a two-day discussion by representatives from Federal agencies, non-profit organizations, and universities involved with generating and synthesizing data about people with developmental and other disabilities. This roundtable addressed programmatic issues such as waiting lists, aging and disability, and employment as well as concrete data and information issues. Data issues included the quality of data states maintain, the focus of information collected on people in institutions and group homes, and who is and should be included in the developmental disabilities population.

ADD has funded successful projects on data and information, including:

- University of Minnesota: National Recurring Data Set Project on Residential Services—Ongoing National and State-by-State Data Collection and Policy/Impact Analysis on Residential Services for Persons with Developmental Disabilities (Charles Lakin: 612/624-5005)
- University of Illinois at Chicago: Sixth National Study of Public Mental Retardation/Developmental Disabilities Spending (David Braddock: 312/413-1647)
- Boston Children's Hospital: Access to Integrated Employment: National Data Collection on Day and Employment Services for Citizens with Developmental Disabilities (William Kiernan: 617/355-6506)

Prevalent throughout the Roundtable discussion was the expanding role of states in the delivery of human services and the differences in what human services they deliver and the substance and extent of such services. For this reason ADD is interested in funding a special study as a part of the public expenditure project. This study would focus on state funding of human services programs for people with disabilities and, in particular, people with developmental disabilities.

ADD anticipates that this additional study will be a 12-month comprehensive investigation and analysis of expenditures at the state level on supports and services for people who have disabilities and, within this population, people who

have developmental disabilities. Such an analysis could be a nation-wide comparison of states or involve a selection of states. The study would not involve income maintenance programs, but would include state expenditures for supports and services relating to housing, medical care, employment or vocational training, transportation, education, including efforts to enhance inclusive education, and personal assistance and other supports for independent living.

ADD's interest in such a study is also based on the devolution of the authorities for human services programs to state governments. The study should demonstrate how states are using their resources to provide supports and services for all people with disabilities and specifically for people with developmental disabilities.

Possible areas of focus for the special study include:

- Describing how services, supports, and assistance available at the state-level ensure accessibility, provide reasonable accommodations and in other ways create community environments to ensure the success of the ADA.
- Comparing states (or selected states) regarding types and comprehensiveness of services and supports.
- Listing services available in some states for replication by other states.

The Roundtable discussion reinforced the significant role the states play in the delivery of human services especially since welfare reform. With its passage has come an increased attention to the employment status of people with disabilities. There is much that still needs to be known about the employment issues impacting on individuals with developmental disabilities. As part of the data project on employment, ADD is proposing information collection and analysis by state on these issues including services and follow-up from state vocational rehabilitation agencies, subsequent long-term employment, and impediments to long-term employment. The use of existing databases funded or maintained by U.S. Department of Education and Labor and others should be utilized in this effort.

The data collection projects on public expenditures, employment, and residential services, should consider including activities which would:

- Identify, collect and disseminate new databases.
- Modify, expand and/or reformulate existing databases.
- Project and model the cost-benefit impact of alternative future decisions based on the analysis of discrete

programmatic options in the areas of residential services and employment.

- Connect, integrate or analyze available databases.

ADD is considering the addition of a data collection project to measure and track the participation of children with developmental disabilities in general education curricula and settings, and spending associated with such inclusion. The project would use existing state and local databases to analyze the relationships between student and family outcomes, program designs and fiscal commitments. Such a project would be intended to help legislatures, advocates, states, local school districts, and school boards understand relationships between program designs and costs so that they can identify the most cost-effective models of program design and delivery of IDEA-funded and locally-funded supports. The goal would be to provide reliable and useful information to support the full inclusion of children with developmental disabilities in American public schools.

*Proposed Fiscal Year 1999 Priority Area 2: Breaking Through the Glass Ceiling to Attain First Class Citizenship*

“The right to enjoying the privileges of membership or citizenship touches all parts of the American Dream and the equality of opportunity envisioned by our founders. The importance of these dreams continues for today's multicultural society: having a home, family and friends; going to school; being a part of the community; and, critically, having a job.” (Presidential Task Force on the Employment of Adults with Disabilities, Re-charting the Course, November 1998)

The May 1998 publication of the “Disability Statistics Abstract” reports that the 1994 Harris poll of Americans with Disabilities indicated that 63 per cent of respondents said their quality of life had improved during the previous four years. However, trend data show only slow improvements in the lives of people with disabilities as measured by such things as more opportunities for employment and improved economic status, greater freedom of movement and ease of access, and increased levels of social integration.

In the release of its 1998 progress report on the status of disability policy, the National Council on Disability stated that “The country continues to move forward, however the rate of progress is slower and less steady than many in the disability community had hoped when the Americans with Disabilities Act (ADA) was enacted in 1990. Federal policy remains rife with

inconsistent messages and unrealistic requirements for people with disabilities who rely on federal programs like Social Security disability benefits, vocational rehabilitation, Medicaid, Medicare, special education, and Temporary Assistance for Needy Families (TANF). In addition, the backlash against civil rights for children and adults with disabilities continues to motivate attempts to weaken laws such as the Individuals with Disabilities Education Act (IDEA) and ADA."

Through Projects of National Significance, in particular, ADD has assisted its grantees in developing and replicating a variety of innovative and successful approaches to increased leadership development and self-determination among people with significant disabilities and their families. Most notably, this has taken the form of early and formative support of such endeavors as Partners in Policymaking, the active participation of families of children with disabilities in the design and implementation 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 who have developmental disabilities.

ADD's programs are State-based, and so are systems that serve Americans with developmental disabilities. In fact, data measuring the delivery of services and supports to people with developmental disabilities and their families show little comparability from State to State. To respond to State flexibility, devolution, and States' ongoing needs for input from stakeholders, DD network programs in most States provide some form of training or leadership development to people with developmental disabilities and their families. Many people have been trained to interact effectively on their own behalf with State systems designed to serve them, and with State policymakers.

However, some issues, problems, programs and systems are inherently national (such as civil rights) or are national in scope (such as the design of federal systems including entitlements). ADD believes that devolution will increase, not decrease the demand for national stakeholders. In order to address the growing need for advocates who have the skills and experience to function in national arenas, ADD proposes to deliver skills-based training to people who have distinguished themselves as graduates of State-based training programs. Although ADD recognizes that many State leaders have developed tremendous skills on their

own over the years, we are particularly interested in providing further training to people who have become experienced, thoughtful, and responsible advocates as a result of State-based training programs.

To address this set of challenges and opportunities, ADD proposes to fund a national policy training academy. The purpose of such an academy would be to provide opportunities for experienced state leaders who are adults with developmental disabilities and families of children with developmental disabilities gain the necessary knowledge and skills to shape and guide the implementation of policies, practices and approaches which enhance their own self determination.

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

- Building a network of individual and family leaders in disability.
- Developing systemic strategies for identifying and involving grassroots disability leaders.
- Disseminating best practices, curricula, guides, and informational materials on self-determination and leadership development.
- Providing experiential learning opportunities that will enable individuals to acquire and deepen their knowledge and skills in the areas of: the operations of the legislative and executive branches; the programs and processes of significant federal agencies; the capacity of computer technology; the resources of national advocacy organizations; grant writing and reviewing; and the development of non-profit organizations.

It is envisioned that the main activities of the Academy will occur in Washington, DC over segments of time to gain the most benefit from national resources. Therefore, ADD is interested in knowing whether DD Councils, UAPs, P&As or other agencies would be willing to provide travel stipends to support participation of local people in this Academy.

*Proposed Fiscal Year 1999 Priority Area 3: Reinventing Quality: Ensuring and Enhancing That Community Living Settings and Services Are Responsive to People With Developmental Disabilities*

• In 1993, the Federal government presented its response to improving how it does business—the National Performance Review, the Federal government's "reinvention" project. When the Review asked Americans

what they expect from government services this is what they heard:

- "Ask us what we want."
- "Don't tell us, 'That's not my department.'"
- "Treat us with courtesy, respect, and enthusiasm."
- "Make it easy."
- "Provide reliable, timely help."

This is the same thing that Americans with disabilities and their families expect from all levels of government. According to a publication issued by the American Association on Mental Retardation (AAMR), "Shaping Our Destiny—A Provider's Guide to Quality Community Services", people with developmental disabilities and their families "should have an equal right to quality services and supports—including clear, relevant service standards, and reliable, timely help." This guide further states that, "Merely delivering services in the community doesn't make them quality services. Community services are quality services when they are flexible, reliable, and complete enough to meet an individual's needs." The guide explains that the old system of service delivery is not based on individually-designed services; that new service standards must be developed that ensure that everybody understands how community services and supports are supposed to work and that the new standards focus on results or outcomes that are meaningful to the people who use the supports. Most importantly, the guide emphasizes that these new service standards do not come from the Federal government, but are the products of each organization's interactions with its customers. Contained in the guide are examples of quality projects and ways to interact with stakeholders by service providers.

The "quality revolution" described in the AAMR publication reflects a trend in the States toward outcome-focused quality assurance systems in residential services for individuals with developmental disabilities. The status of the States' activities toward implementing an outcome-based approach was the subject of a 1996 report "Compendium of State Outcome-Focused Quality Assurance Systems" by the Human Services Research Institute (HSRI). It found that there was a general sense in the States "that traditional quality assurance, in particular comprehensive licensure and certification surveys, focuses too heavily on environment and process and not enough on outcomes for the individual (consumer) or on 'quality of life' issues. Across the States there appears to be a relationship between the evolution of

the State's mental retardation/developmental disabilities service system and the degree of quality assurance reform toward an outcome-focused system."

"Reinventing Quality—The 1998 Sourcebook of Innovative Programs for the Quality Assurance and Quality Improvement of Community Services", Institute on Community Integration/University of Minnesota, reaffirms this trend in the States as reported by HSRI and reasserts the need to change the service standards to reflect the evolution to community-based, individual needs. In the background section of this book, it states "Recent years have seen a shift in long-term care for persons with developmental disabilities from large institutions to community settings. But people receiving community services can fully realize the potential for improved quality of life afforded by this movement only if quality assurance expectations and activities are changed significantly from those originally developed for institutional care." Efforts to improve the quality of community services have demonstrated many innovative and comprehensive quality assessment and enhancement practices that are contained in the Sourcebook. It is these efforts that "may help others to fashion their own responses that not only protect the basic safety and well-being of individuals, but also encourage and support their preferred choices, personal growth, and individual lifestyles." One set of efforts described is consumer and family monitoring initiatives. Eight programs are profiled outlining their attempts at gaining insight into the quality of life of residents at group homes and other smaller facilities and providing feedback for quality enhancement.

It is obvious that "monitoring" in the traditional sense of the word is no longer an acceptable method for determining the quality of services and supports to people with developmental disabilities and their families. Thus, ADD is very interested in supporting models that demonstrate the effectiveness and cost efficiency of using volunteer surveyors of community residencies to gather objective information on the quality of life or outcomes experienced by their residents. The purpose of these projects would be to assist in the development of quality assurance improvements in their states. Projects should consider how their activities could contribute to an integrated service system based on person-centered outcomes. Any tools or instruments of measurement used should have as their focus the needs of the individual. These tools or

instruments should be tested for reliability or validity and be standardized. Also, any tools/instruments should offer interpretive guidelines for those expected to use them. These projects would be expected to include in their community surveying multiple community settings (rural and urban), different types of housing (group homes, supported living, ownership) and all ranges of disability from mild to severe, especially those with limited communication skills. Projects should address cultural and geographic issues in their surveying as well. Consideration should be given to any issues regarding liability and insurance that may effect the implementation of the project. Models that ADD would seriously consider for funding should incorporate recruitment of consumers and family members and advocates, training of prospective surveyors, and direct observation and contact of residents.

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

Dated: April 14, 1999.

**Sue Swenson,**

*Commissioner, Administration on Developmental Disabilities.*

[FR Doc. 99-9862 Filed 4-19-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Head Start Bureau; Advisory Committee on Head Start Research and Evaluation; Notice of Meeting; Correction

**AGENCY:** Administration on Children, Youth and Families, ACF, DHHS.

**ACTION:** Correction.

**SUMMARY:** On Monday, April 5, 1999, a Notice was published in the **Federal Register**, document 99-8316, page 16470 announcing the Advisory Committee on Head Start Research and Evaluation meeting to be held on April 26-27, 1999 at Georgetown University. The Head Start Web site was incorrectly cited as <http://www/dhhs.gov/programs/hsb>. The correct web site is <http://www2.acf.dhhs.gov/programs/hsb>. For further information contact Deborah Roderick Stark at 301/889-0430.

Dated: April 12, 1999.

**Patricia Montoya,**

*Commissioner, Administration on Children, Youth, and Families.*

[FR Doc. 99-9861 Filed 4-19-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 77N-0240; DESI 1786]

#### Certain Single-Entity Coronary Vasodilators Containing Controlled-Release Nitroglycerin; Opportunity for a Hearing

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to withdraw approval of 23 new drug applications (NDA's) and abbreviated new drug applications (ANDA's) for certain single-entity coronary vasodilator drug products containing controlled-release nitroglycerin. FDA is offering the holders of the applications an opportunity for a hearing on the proposal. The basis for the proposal is that the sponsors of these products have failed to submit acceptable data on bioavailability and bioequivalence.

**DATES:** Hearing requests are due by May 20, 1999; data and information in support of hearing requests are due by June 21, 1999.

**ADDRESSES:** Communications in response to this notice should be identified with the reference number DESI 1786, and directed to the attention of the appropriate office named as follows:

A request for a hearing, supporting data, and other comments are to be identified with Docket No. 77N-0240 and submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

A request for applicability of this notice to a specific product should be directed to the Division of Prescription Drug Compliance and Surveillance (HFD-330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

**FOR FURTHER INFORMATION CONTACT:** Mary E. Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers