

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.

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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.

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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