administrative policy changes spread over several decades.'' (GAO, 1996)

Nevertheless, many (though not all) of the Medicaid questions to which people need answers are repetitive and sometimes simple. Clear, honest, user-friendly answers to frequently asked questions are often a feature of Web sites on any topic and may be one of the best uses of the Internet.

ADD is proposing to fund one project to build an Internet site that will provide relevant content and attractive information on what is possible under the Medicaid program. The site should be user-friendly and useful to a broad range of users, including people with developmental and other related disabilities, their families, their advocates, DD network members, state policymakers, regional HCFA staff, and other interested persons. The site should be responsive to the needs and wants of its users, and should collect and measure user satisfaction. It should post frequently asked questions (FAQs) about Medicaid with their answers, and should encourage frank and open ''human'' interchanges between users. The site must be accessible to people with a broad range of disabilities. Proposing organizations must show that they (1) are credible sources of information to people with developmental disabilities and (2) that they intend to comply with accessibility standards and go beyond compliance to improve access as much as possible. Special care should be taken to make the site useful and attractive to young persons with developmental and other disabilities.

Proposed Fiscal Year 2000 Priority Area 3: Managing Our Program Knowledge Through Web Improvement

The Developmental Disabilities Assistance and Bill of Rights Act (DD Act) provides authorization for three State Programs and a national program that seek to increase the independence, productivity, and inclusion of persons with developmental disabilities.

A Developmental Disabilities Council (DD Council) in each State promotes, through systemic change, capacity building, and advocacy activities, the development of a comprehensive consumer-centered system of coordinated and culturally competent services, supports, and other assistance. The priority areas addressed by DD Councils include employment, community living, child development, and system coordination and community education.

The Protection and Advocacy (P&A) System provides for the protection and advocacy of legal and human rights. The P&A System advocate on behalf of, and provide advocacy services to persons with developmental disabilities in issue areas related to their disabilities, including: education, abuse and neglect, institutional and habitation services, guardianship issues, and housing issues.

The University Affiliated Program (UAPs) are public and private non-profit agencies in the States and territories, each affiliated with a university. Each UAP receives annual discretionary funding for operational and administrative support, which provides a platform for interdisciplinary training, clinical and community-based service activities, technical assistance to community services personnel, and information/dissemination activities.

In addition to State-based programs, ADD funds research and demonstration grants in an effort to address and increase our understanding of issues of national scope. The Projects of National Significance (PNS) program focuses on the most pressing issues affecting people with developmental disabilities and their families. Project issues transcend the borders of States and territories, while project designs are oriented to permit local implementation of practical solutions.

Each of these programs has a uniqueness and breadth of knowledge that if managed through modern technology would result in a knowledge resource warehouse. The nation cannot afford a digital divide between these programs and between these programs and those they serve. With these programs in mind, ADD is interested in funding a project for the development or enhancement of a model website whose design features are easily employable by each program; its approach on the cutting edge. It should be seen as the beginning of a new form of cyber architecture with a focus on continuous improvement that will enable those programs to improve their use of the web and their ability to hyperlink to others.

This new model website would enhance the ability of ADD's programs to exchange information and build upon ongoing diverse enterprises throughout the developmental disabilities community. At the same time, the contributions and achievements of these programs towards the quality of life of persons with disabilities and their families should be easily disseminated and accessible. It should support the development of strategies, technologies, and media channels for the management of knowledge generated/produced by these programs. This site should operate as an information center as well as a networking tool for the programs and others. This website is not about outcomes exclusively but content and access to content that affects the lives of people with developmental disabilities and their families. ADD envisions that the first year would begin with the UAPs and the PNS projects with the understanding the model website be inclusive of the other programs over the duration of the project. It is expected that the site would be open to everyone; including the average citizen, people working in each program, and people working in related programs. Also, it should be accessible to people with a broad range of disabilities utilizing the most current accessibility standards. ADD would be supportive of applicants that represent a consortia of UAPSs and DD Councils.

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

Dated: April 7, 2000.

Sue Swenson,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 00–9748 Filed 4–18–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4202]

Agency Information Collection Activities; Announcement of OMB Approval; Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 2, 2000 (65 FR 4979), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An

agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0338. The approval expires on March 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: April 12, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–9714 Filed 4–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0969]

Risk Assessment of the Public Health Impact of Streptogramin Resistance in Enterococcus faecium Attributable to the Use of Streptogramins in Animals; Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), is announcing plans to develop a prototypic risk assessment (RA) model that accounts for the transfer of resistance determinants from bacteria in food-producing animals to bacteria in humans. The agency requests comments on their approach to the RA model and requests that scientific data and information relevant to the conduct of the RA be submitted. This model will be applied to assess the association between the development of streptogramin (quinupristin/dalfopristin (QD)) resistant *Enterococcus faecium* in humans and the use of virginiamycin in food-producing animals. The center will attempt to use the RA model to quantify the human health impact attributable both to direct acquisition of resistant *E. faecium* from food-producing animals and to the transfer of resistance determinants from *E. faecium* in food-producing animals to *E. faecium* in humans.

DATES: Submit written comments, scientific data, and information by June 19, 2000.

ADDRESSES: Single copies of ''A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (hereinafter referred to as the Framework Document) is discussed in the **SUPPLEMENTARY INFORMATION** section of this document and may be obtained by writing to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your request. This document is also available through CVM's homepage on the Internet at http://www.fda.gov/cvm/fda/mappgs/antitoc.html. Submit written comments, scientific data, and information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nicholas E. Weber, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6986, FAX 301–594–2298, or e-mail nweber@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the**Federal Register** of January 6, 1999 (64 FR 887), FDA published a notice of availability of a discussion paper (the Framework Document). This Framework Document sets out a conceptual risk-based process for evaluating the microbial safety of antimicrobial drugs intended for use in food-producing animals. The proposed RA furthers the tenets of the Framework Document by developing a RA model to quantify the potential human health impact of resistant bacteria acquired from animals via food.

Thus, CVM proposes to conduct its second antimicrobial resistance RA. A draft of CVM's first antimicrobial resistance RA model and associated documents are available on CVM's homepage on the Internet at http://www.fda.gov/cvm/fda/mappgs/ra/risk.html. The first RA modeled the human health impact of fluoroquinolone resistant *Campylobacter* infections associated with the consumption of chicken. CVM proposes to develop a second RA that will account for both the acquisition of resistant bacteria and the transfer of resistance determinants from bacteria in food-producing animals to bacteria in humans. This model will be applied to assess the association between the presence of streptogramin (QD) resistant *Enterococci faecium* in humans and the use of streptogramins (virginiamycin) in food-producing animals as an example of risk attributed to transference of resistance determinants.

In September 1999, FDA's Center for Drug Evaluation and Research approved Synercid™, a streptogramin (QD), for use in human medicine for treatment of vancomycin resistant *E. faecium* (VREF) bacteremias as well as for treatment of *Staphylococcus aureus* and *Streptococcus pyogenes* skin and soft tissue infections. At the current time, QD is considered to be the last line of therapy for VREF. Another streptogramin, virginiamycin, has been used in food-producing animals for 26 years. The initial approval was for chickens, but virginiamycin was subsequently approved for use in turkeys, swine, and most recently in cattle. This RA will seek to quantify the public-health risk attributable to the use of virginiamycin in food-producing animals. *Enterococcus faecium* that develop resistance due to exposure to virginiamycin also demonstrate reduced susceptibility to QD. These resistant strains of *E. faecium* can contaminate meat products and thereby enter the human intestine. It is thought that these resistant strains contaminating meat products may cause problems for the human in two major ways: By becoming host-adapted or by transferring resistance determinants to endogenous human *E. faecium*.

It is generally believed that the indigenous intestinal microflora of healthy humans inhibit colonization by bacteria from exogenous sources. In the case of illness requiring antibiotic therapy however, associated perturbations due to drug treatment may result in colonization by organisms not included in the flora of healthy individuals. This scenario could result in the intestinal colonization and proliferation of antibiotic resistant bacteria from the external environment. Enterococcal infections comprise 20 to 30 percent of over 2 million hospital-acquired infections per year in the United States (Ref. 1). VREF infections are almost exclusively hospital infections and account for about 14 percent of all enterococcal infections, although this varies widely (5 to 70 percent) from hospital to hospital, according to hospital vancomycin use, teaching versus nonteaching hospital status, and hospital size (number of beds) (Refs. 1 and 2). This translates to about 70,000 VREF infections per year which will most likely be treated with QD . Among VREF bacteremic patients treated with QD, emerging resistance