DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration for Developmental Disabilities

Award To: Oregon Health & Science University, Child Development & Rehabilitation Center.

Purpose: To supplement a grant award for support of “Making It Real: Participatory Action Research (PAR) for University Centers for Excellence in Developmental Disabilities (UCEDDs)”.

Amount of Award: $65,000 for one year.


Justification for Exception to Competition: After consulting with relevant, informed sources, including individuals with developmental disabilities and their families, the Administration for Developmental Disabilities (ADD) determined that it was beneficial to continue funding the Oregon Health & Science University, Child Development & Rehabilitation Center project to strengthen and expand the inclusion of people with developmental disabilities and their family members in participatory action research projects at University Centers for Excellence in Developmental Disabilities (UCEDDs).

The Oregon Institute on Disability & Development, the Oregon Health & Science University, Child Development and Rehabilitation Center will receive a sole source program expansion supplemental grant for “Making It Real: Participatory Action Research (PAR) for UCEDDs,” a training initiative on the critical and emerging needs of individuals with developmental disabilities and their families. Through the project, a tool kit is being created that will include tested educational modules on participatory action research. Through the creation of the toolkit, every UCEDD will be able to access resources that will enhance and increase PAR and support initiatives that are most meaningful to people with developmental disabilities and their families. It will also be available to individuals with developmental disabilities, family members, advocacy groups, and other interested organizations. By continuing funding of this project, additional resources will be developed, including materials in Spanish. In addition, the expansion supplement will allow for more time and resources to enhance training and dissemination efforts.

The Administration for Children and Families intends to supplement the current grant by $65,000. The grantee will continue to provide a 25 percent match.

FOR FURTHER INFORMATION CONTACT: Jennifer G. Johnson, Ed.D., Program Specialist, Administration on Developmental Disabilities, 200 Independence Avenue, SW., Room 405-D, Washington, DC 20201. Telephone: 202/690–5982 (v); 202/205–8037 (t). E-mail: jennifer.johnson@acf.hhs.gov.


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Human-Labeled Drugs Distributed and Used in Animal Medicine; Withdrawal of Compliance Policy Guide

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a compliance policy guide (CPG) that was issued on March 19, 1991.

DATES: July 7, 2006.

FOR FURTHER INFORMATION CONTACT: Diane D. Jeang, Division of Compliance Policy (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6833.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 30, 1992 (57 FR 33729), FDA announced the availability of a revised CPG 7125.35 entitled “Human-Labeled Drugs Distributed and Used in Animal Medicine.” The CPG is being withdrawn because it is obsolete. This CPG explained how FDA would exercise its enforcement discretion with respect to the distribution and use of human-labeled drug products for use in animals.

The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) was signed into law on October 22, 1994. AMDUCA allows veterinarians to prescribe extralabel uses of approved animal drugs and approved human drugs for animals under certain conditions. An extralabel use must be by or on the order of a licensed veterinarian within the context of a veterinarian-client-patient relationship and must be in conformance with the implementing regulations published in part 530 (21 CFR part 530). A list of drugs specifically prohibited from extralabel use in animals is in § 530.41.

With the enactment of AMDUCA and the issuance of implementing regulations, FDA is withdrawing CPG 7125.35 because it is obsolete. On September 24, 1998, a CPG section 615.100 entitled “Extralabel Use of New Animal Drugs in Food-Producing Animals (CPG 7125.06)” was withdrawn for the same reason (63 FR 51074).

Dated: June 20, 2006.

Margaret O’K. Glavin,
Associate Commissioner for Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Streptomycin Residues in Cattle Tissues; Withdrawal of Compliance Policy Guide

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the compliance policy guide (CPG) entitled “Sec. 616.100 Streptomycin Residues in Cattle Tissues (CPG 7125.22)” This CPG is obsolete.

DATES: The withdrawal is effective July 7, 2006.

FOR FURTHER INFORMATION CONTACT: Diane D. Jeang, Division of Compliance Policy (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6833.

SUPPLEMENTARY INFORMATION: FDA issued the CPG entitled “Sec. 616.100 Streptomycin Residues in Cattle Tissues (CPG 7125.22)” on October 1, 1980. The CPG was issued because there were no published tolerances for residues of streptomycin in cattle tissue and the available data supported an action level of 2 part per million (ppm) streptomycin/dihydrostreptomycin.