DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–374–000]

PG&E Gas Transmission, Northwest Corporation; Notice of Proposed Change in FERC Gas Tariff

April 13, 2001.

Take notice that on April 10, 2001, PG&E Gas Transmission, Northwest Corporation (GTN) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1–A, Thirty-first Revised Sheet No. 4, to become effective April 1, 2001.

GTN states that the purpose of this filing is to request a reduction in its Mitigation Revenue Recovery Surcharge (MRRS) in compliance with the requirements of its Settlement in Docket Nos. RP94–149–000, et al. In addition, GTN is filing to reduce its Competitive Equalization Surcharge, which was designed to mirror the MRRS and apply to new expansion shippers subscribing to long-term firm capacity on GTN.

GTN further states that a copy of this filing has been served on GTN's jurisdictional customers and interested state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–9704 Filed 4–18–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–1682–000]

Southwest Regional Transmission Association; Notice of Filing

April 13, 2001.

Take notice that on March 27, 2001, Southwest Regional Transmission Association (SWRTA) tendered for filing Withdrawal from Membership of the Tonopah Irrigation District effective June 30, 2001.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before April 20, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–9658 Filed 4–18–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 66 FR 14904–14906, dated March 14, 2001) is amended to reflect the establishment of the National Center on Birth Defects and Developmental Disabilities within the Centers for Disease Control and Prevention.

The Children's Health Act of 2000, passed by the U.S. Congress and signed into law by the President on October 17, 2000, requires the establishment of the National Center on Birth Defects and Developmental Disabilities at CDC by April 15, 2001. As specified in the Act, CDC will include in the new Center the programs, functions, and staff of the current Division of Birth Defects and Developmental Disabilities (DBDDD), National Center for Environmental Health (NCEH). Consequently, DBDDD will be abolished as an organizational component of NCEH and established as the National Center on Birth Defects and Developmental Disabilities. Congressional intent of the Act is focused on incorporating birth defects and developmental disabilities, as well as adult disabilities and secondary prevention programs, in the new Center.

Section C–B, Organization and Functions, is hereby amended as follows:

After the mission statement for the *Division of Acute Care, Rehabilitation Research, and Disability Prevention (CE6), National Center for Injury Prevention and Control (CE),* insert the following:

National Center on Birth Defects and Developmental Disabilities (CF)

The mission of the National Center on Birth Defects and Developmental Disabilities (NCBDDD) is to improve the health of children and adults by preventing birth defects and developmental disabilities, promoting optimal child development, and the health and wellness among children and adults living with disabilities. In carrying out this mission, this organization: (1) Conducts public health research, epidemiological investigations, and program demonstrations directed toward preventing birth defects and developmental disabilities, optimal fetal, infant, and child development, and promoting the health and wellness of people with disabilities, including the prevention of secondary conditions; (2) plans, develops, establishes, and maintains systems of surveillance and monitoring the population for these conditions; (3) operates regional centers for the conduct of applied epidemiological research on these conditions; (4) provides information and education to health care providers, public health professionals, and the public on these conditions; (5) provides technical assistance, consultation, capacity building through technology transfer, grants, cooperative agreements, contracts, and other means to State, local, international, and nonprofit organizations to prevent and control these

conditions; (6) provides training in the epidemiology of these conditions for health professionals within and outside the United States; (7) translates scientific findings into intervention, prevention, and health promotion strategies; (8) conducts evaluations of programs to determine effectiveness; and (9) coordinates activities with other CDC organizations and federal and non-federal health agencies, as appropriate.

Delete in their entirety the title and mission statement for the *Division of Birth Defects and Developmental Disabilities (CN5), National Center for Environmental Health (CN).*

Section C–D, Delegations of Authority. All delegations and redelegations of authority to any officers or employees which were in effect immediately prior to this reorganization and which are consistent with this reorganization shall continue in effect pending further redelegation.

Dated: April 12, 2001.

Jeffrey P. Koplan,

Director.

[FR Doc. 01–9739 Filed 4–18–01; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0785]

Guidance on Medical Device Patient Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Guidance on Medical Device Patient Labeling.'' This guidance describes how to make medical device patient labeling understandable to and usable by patients (or family members or other lay persons caring for patients). It is intended to assist manufacturers in their development and reviewers in their review and evaluation of medical device patient labeling. This guidance is designed to help assure safe and effective use of medical devices through medical device patient labeling that informs patients or their lay caregivers about proper use, risks, and benefits of the device in language they can understand.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Guidance on Medical Device Patient Labeling'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Paula G. Silberberg, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–1217.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance provides information on the content, format, and organization of information that patients need to use medical devices safely and effectively. It also gives principles for writing and presenting patient information in a manner most understandable and usable to patients and their lay caregivers. With an increase in patient use of complex medical devices previously used primarily by skilled and knowledgeable health-care professionals, effective medical device patient labeling has become increasingly important to help assure the safe and effective use of devices. This guidance document was published for public comment on March 3, 2000, as a draft proposal entitled ''Guidance on Medical Device Patient Labeling.''

Both the draft guidance document and the March 2000 notice provided an opportunity for public comment, which closed June 2, 2000. Based on the comments received, the following substantive changes have been incorporated into the final version of the guidance.

1. FDA inserted a paragraph in ''What is the purpose of this guidance?'' explaining that when translating the professional label into lay language, care should be taken to ensure that the lay language does not alter the intent of the indications, contraindications, warnings and precautions, or other parts of the labeling.

2. The sections ''When should you use medical device patient labeling?'' and ''Determining Sequence and Content'' were restructured and revised for clarity. Both sections were clarified to focus on the needs of the specific target population for the device rather than an inflexible formula.

3. The section entitled ''Alternatives to the device and treatment'' was deleted.

4. Changes were made to address the safe and proper methods of disposing of medical devices.

5. FDA has clarified that clinical studies information can be provided either as part of the patient labeling, or upon request.

II. Significance of Guidance

This guidance document represents the agency's current thinking on medical device patient labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

The agency has adopted the good guidance practices (GGP's) regulation, which sets forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance on Medical Device Patient Labeling'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2 and then enter the document number (1128) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Guidance on Medical Device Patient Labeling,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information.