

U.S. Patent Application SN 60/085,260
(CDC Ref. #: I-005-97/0)

Ore Pass Level and Blockage Locator Device

This invention comprises of a device that consists of weldable strain gauges attached to inexpensive steel strapping that can be bolted to the interior of an ore pass. This device provides multiple measurement points for the entire length of the ore pass and indicates the ore level in the ore pass and the location of any blockages or hang-ups. Consequently, this information can reduce accidents associated with removing hang-ups by providing an indication of the entire length of the ore pass and indicates the ore level in the ore pass and the location of any blockages or hang-ups.

Inventor: Todd M. Ruff

U.S. Patent Application SN: 60/086,929
(CDC Ref. #: I-006-98/0)

Method for Determination of Hexavalent Chromium Using Ultrasonication and Storing Anion Exchange Solid Phase Extraction

A method for the determination of hexavalent chromium in environmental and industrial hygiene samples is provided. Based on the chemical properties of chromium species in aqueous solutions, a simple, fast, sensitive, and economical field method has been developed and evaluated for the determination of hexavalent chromium. By means of ultrasonic extraction in combination with a strong anion exchange solid phase extraction (SAE-SPE) technique, the filtration, preconcentration, and isolation of the hexavalent chromium in the presence of other chromium species and interferences was achieved. This method can be used in both laboratory and field analysis.

Inventor: Jin Wang, et al.

U.S. Patent Application SN: 60/076,137
(CDC Ref. #: I-010-98/0)

Intrinsically-Safe Hazard Alert Module

This invention relates to an intrinsically-safe roof hazard warning device designed to be attached to the roof hazard warning device designed to be attached to the roof of a mine to indicate unsupported roof or other unsafe conditions. The hazard alert can then direct a person's attention to read the warning message on the module, and thus avoiding the hazard beyond the device. The device of this invention is especially useful in underground mining operations.

Inventor: William D. Mayercheck, et al.
U.S. Patent Application SN: 60/083,677
(CDC Ref. #: I-012-98/0)

Method and Apparatus for Detecting a Temperature Increase in an Electrical Insulator

This invention provides a heat-sensitive warning device and a related method for visually detecting an increase in the temperature of the outer surface of an electrical insulator, which may indicate the unsafe flow of leakage of electrical current. Furthermore, the method and apparatus of the invention provides visual indicia of a temperature increase in the electrical insulator, where this preset temperature is well below an unsafe temperature for the particular electrical insulator so that the insulator may be replaced prior to reaching the unsafe temperature. This invention is particularly useful in underground mining operations.

Inventor: Arthur J. Hudson

U.S. Patent Application SN: 60/087,131
(CDC Ref. #: I-016-97/0)

Method and Apparatus for Load Rate Monitoring

This device monitors the dynamic loading rate on support systems used in underground mines. The device uses a programmable microcontroller to monitor and calculate the loading rates on the support system from pressure transducer(s) or weldable strain gage(s) instrumentation installed on the support system. Furthermore, this invention is programmed to sequentially activate different colored lights and audio alarms as the loading rate increases on the support system. This information can be used as an aid in determining when to install additional support or in determining when to remove equipment and/or personnel from the area before a dangerous roof fall occurs.

Inventor: Wayne Howie, et al.

U.S. Patent Application SN: 60/083,678
(CDC Ref. #: I-016-98/0)

Instrumented Cable

The invention describes a novel way of removing a king wire in a cable bolt and molding a new cable bolt king wire with strain gauges on it to measure strain in the cable bolt from the loads applied to the cable. The disclosed method consists of using a piece of strap metal with strain gauges attached to it as the basic wire replacement. This assembly is placed in an injector mold and injected with a nonspecified forming compound to make the attachment for the new instrumented king wire.

Inventor: Lewis A. Martin, et al.

U.S. Patent Application SN: 60/076,138
(CDC Ref. #: I-023-97/0)

Dated: May 10, 1999.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99-12208 Filed 5-13-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Grant of Exclusive License: Dust Detector Tube

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(c) and 37 CFR 404.7(a) that the Centers for Disease Control and Prevention (CDC), Technology Transfer Office, Department of Health and Human Services (DHHS), is contemplating the grant of a worldwide, limited field of use, exclusive license to practice the invention embodied in the patent application referred to below to SKC, Inc., having a place of business in Eighty-Four, Pennsylvania. The patent rights in this invention have been assigned to the government of the United States of America. The patent application to license is:

Title: Dust Detector Tube.

U.S. Patent Application Serial No.: 60/052,719.

Filing Date: 7.3.97.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

Current methods of airborne dust sampling and detection require expensive instantaneous and short-term monitors or gravimetric filters. Current gravimetric dust filtering techniques are cumbersome. A need exists for an inexpensive and noncumbersome method to detect personal dust exposure to aid in assuring the respiratory health of workers.

CDC scientists at the Pittsburgh Research Laboratory have invented a dust detection tube device that provides an individual sampling method and apparatus for real-time respirable dust dosimetry for dust exposure assessment. This device can be standardized with other types of gas detection tubes so that it can be used with the same pump system to measure both dust and gas.

ADDRESSES: Requests for a copy of this patent application, inquiries, comments,

and other materials relating to the contemplated license should be directed to Thomas E. O'Toole, Deputy Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Mailstop E-67, Atlanta, GA 30333, telephone: (404) 639-6270; facsimile: (404) 639-6266. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within sixty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

Dated: May 10, 1999.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99-12206 Filed 5-13-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0389]

Final Guidance on FDA Approval of New Animal Drugs for Minor Uses and for Minor Species; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled "Guidance for Industry: FDA Approval of New Animal Drugs for Minor Uses and for Minor Species." This guidance document is intended to provide specific guidance on the means for generating effectiveness and safety data to support the approval of new animal drugs for minor uses and minor species.

DATES: Written comments may be provided at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Guidance for Industry: FDA Approval of New Animal Drugs for Minor Uses and for Minor Species" to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500

Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. Copies of this guidance document may also be obtained from the CVM home page at "http://www.fda.gov/cvm". Submit written comments on the guidance document to the Policy and Regulations Team (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT:

Margaret R. Oeller, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7581, e-mail: moeller@bangate.fda.gov.

SUPPLEMENTARY INFORMATION: The major purpose of this guidance document is to suggest means of generating effectiveness and safety data to support the approval of minor use new animal drugs. Minor use of a new animal drug is defined as use in a minor species or use in any animal species for a condition that is rare or that occurs in limited geographic areas. Minor species are defined by exclusion, as any species other than major species. Major species are defined as cattle, swine, chickens, turkeys, horses, dogs, and cats.

According to current regulations, sheep are a minor species except with respect to human food safety data collection requirements, for which sheep are considered major species.

The guidance document, as applied to minor use new animal drugs, does not lessen the legal requirements for demonstrating the safety and effectiveness of a new animal drug. Instead, the guidance document suggests possible means of generating safety and effectiveness data to satisfy these requirements.

In the **Federal Register** of September 29, 1997 (62 FR 50952), FDA published a notice of availability of a draft guidance on this subject. The notice gave interested persons an opportunity to submit comments by December 29, 1997. Seven comments were received by industry and trade associations. FDA considered these comments and revised the draft guidance document where appropriate.

This guidance document is intended to reflect the current way that animal drugs are approved for minor species and minor uses. The Animal Drug Availability Act of 1996 required CVM to examine the way that these products are approved and to propose means to facilitate such approvals. In the **Federal Register** of October 29, 1998 (63 FR 58056), CVM published a notice of the availability of its report proposing several options to encourage animal

drug approvals for minor species and for minor uses. It is very likely that additional policies and programs will be implemented over the next few years to accomplish this goal. Because policies and programs may change, sponsors are encouraged to contact CVM early in project development to determine the most efficient path to approval of their products. If any program and policy changes affect the policies in this guidance, CVM will revise this final guidance.

The final guidance represents the agency's current thinking on the means of generating efficacy and safety data to support approval of new animal drug applications for minor use new animal drugs. 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 requirements of the applicable statute, regulations, or both. As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. CVM will periodically review the comments concerning the document and, when appropriate, amend the guidance.

Dated: May 5, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-12179 Filed 5-13-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1089]

Year 2000 (Y2K) Computer Compliance Guide; Guidance for FDA Personnel

AGENCY: Food and Drug Administration

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new compliance policy guide (CPG) entitled "Year 2000 (Y2K) Computer Compliance" (section 160-800). This guidance document represents the agency's current thinking on the manufacturing and distribution of domestic and imported products regulated by FDA using computer systems that may not perform properly before, or during, the transition to the year 2000 (Y2K). The text of the CPG is included in this notice. This compliance guidance document is an update to the Compliance Policy Guides Manual (August 1996 edition). It is a new CPG,