

improve CDC's understanding of minority issues related to the epidemic

of HIV, target educational efforts to prevent transmission, and improve

services for persons with HIV infection. The total annual burden hours are 3500.

#### DATA FOR CALENDAR YEAR 1998

Respondents	No. of respondents	No. of responses/re-spondent	Avg. burden of response (in hrs.)
Georgia .....	292	1	.75
California .....	301	1	.75
Michigan .....	82	1	.75
New Mexico .....	81	1	.75
Arizona .....	165	1	.75
Colorado .....	139	1	.75
Connecticut .....	229	1	.75
Delaware .....	43	1	.75
Florida .....	430	1	.75
S. Carolina .....	270	1	.75
New Jersey .....	86	1	.75
Washington .....	160	1	.75

Dated: January 14, 2000.

**Nancy Cheal, Ph.D.,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Disease Control and Prevention

[30DAY-11-00]

##### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

##### Proposed Project

Specifications and Tests for Approval of Coal Mine Dust Personal Sampler Units—(0920-0148)—Extension—National Institute for Occupational Safety and Health (NIOSH)—Under the Federal Coal Mine Health & Safety Act of 1977, PL91-173 (amended the Federal Coal Mine & Safety Act of 1969), mine operators must periodically sample mine atmospheres and submit the samples to the Mine Safety and Health Administration (MSHA). The Act

states that sampling equipment used must be approved by the Secretaries of the Department of Health and Human Services (DHHS) and the Department of Labor (DOL). Concurrent permissibility approval for electrical intrinsic safety is provided by MSHA while NIOSH certifies the performance under Title 30 CFR Part 74. Under this regulation, certification applicants are required to submit detailed parts lists, drawings, and inspection instructions, along with the personal sampler unit to be tested. These materials are provided to NIOSH along with a letter from the applicant requesting certification. After NIOSH has tested the unit and certifies the performance of the equipment, a certificate of approval is issued to the manufacturer. Should the equipment be disapproved, a letter is sent to the manufacturer outlining the details of the defects resulting in disapproval, with suggestions for possible corrections to the unit. Certificates of approval are accompanied by photographs of designs for approval labels to be affixed to each coal mine dust personal sampler unit. Use of the approval label is authorized only on sampler units which conform strictly with the drawings and specifications upon which the certificate of approval is based. Changes or modifications in the unit after certification will result in the manufacturer requesting extensions of approval through the original certification process.

The information is used by NIOSH to fulfill its legislatively-mandated responsibilities to evaluate and approve coal mine dust personal sampler units (CMDPSU) submitted for certification and approval actions (30 U.S.C. 957 and 961). Before NIOSH grants a certification, it must have sufficient evidence of safety and adequate

performance. The parts listing, engineering drawings, and inspection instructions submitted are used by NIOSH to assure that descriptions of tested units are fully detailed and that future units produced are equivalent to those currently certified. Without the information specified in 30 CFR Part 74, NIOSH will be unable to adequately evaluate CMDPSU safety and efficacy, and to determine if functional changes were made in the manufacture of certified products. The total annual burden hours are 44.

Respondents	No. of re-spond-ents	No. of re-sponses/re-spond-ent	Avg. burden of re-sponse (in hrs.)
Manufacturer ....	1	1	44

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**Nancy Cheal, Ph.D.,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Disease Control and Prevention

[30DAY-12-00]

##### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the

Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

### Proposed Project

1. A Pilot Study to Evaluate CDC's 1998 Guidelines for the Treatment of Sexually Transmitted Diseases Among Clinicians in Two Managed Care Organizations—The National Center for HIV, STD, and TB Prevention (NCHSTP) is proposing a pilot survey of 1,000 practitioners in two managed care plans to evaluate how CDC's most recent edition (1998) of the Sexually Transmitted Disease (STD) Treatment Guidelines influence practice. The pilot survey will be conducted in two large, mixed model managed care plans which are located in two different geographic regions of the U.S. The survey is expected to last from 3–6 months. The CDC periodically publishes national guidelines on the diagnosis and treatment of sexually transmitted diseases; however, little is known about the impact of the guidelines on clinical practice and treatment choices, the practical use of the guidelines, or utility to providers. Data gathered from this study will provide preliminary information about the extent to which providers are aware of the guidelines, their access to the guidelines, their use of the guidelines, and factors that enable or preclude use of the guidelines. The information will assist CDC in determining ways to improve practitioners' understanding and promote utilization of the guidelines; determine ways to make them more available for medical practitioners; and increase the use of the guidelines in appropriate medical practices. The total annual burden hours are 334.

Respondents	No. of re-spond-ents	No. of re-sponses/ respond-ent	Avg. bur-den/re-sponse (in hours)
Managed care physicians or advance practice Nurses .....	1,000	1	.334

Dated: January 14, 2000.

**Nancy Cheal, Ph.D.,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 94N-0162]

#### Premchand Girdhari; Denial of Hearing; Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is denying the request of Premchand Girdhari, 643 Rassbach St., Eau Claire, WI 54701, for a hearing, and is issuing a final order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Girdhari from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Girdhari was convicted of two felonies under Federal law relating to the regulation of a drug product under the act. Mr. Girdhari has failed to file with the agency information and analyses sufficient to create a basis for a hearing concerning this action.

**EFFECTIVE DATE:** January 21, 2000.

**ADDRESSES:** Application for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Richard L. Arkin, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl. Rockville, MD 20855, 301-827-0141, FAX 301-827-5510, e-mail "rarkin@bangate.fda.gov".

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On May 8, 1991, United States District Court for the Western District of Wisconsin accepted a plea of guilty from Premchand Girdhari, former President of Radix Laboratories, Inc., to a two count information, for making false statements and distributing adulterated drugs with the intent to defraud and mislead in violation of the act, Federal felony offenses under 18 U.S.C. 1001 and sections 301(a) and

303(b) of the act (21 U.S.C. 331(a) and 333(b)). On July 8, 1991, judgment against Mr. Girdhari was entered and the court advised him of his sentence. The court amended its judgment to correct a clerical error but otherwise affirmed its earlier judgment and sentence on October 7, 1991.

Mr. Girdhari was the president of Radix Laboratories, Inc., a Wisconsin corporation that manufactured a variety of animal drugs. In that capacity, he caused to be introduced into commerce adulterated drugs. Specifically, Mr. Girdhari marketed the drug "Antihistamine (2%)," which drug is adulterated within the meaning of (section 501(a)(5) and (a)(2)(B) of the act (21 U.S.C. 351(a)(5) and (a)(2)(B)), because the drug was not the subject of the necessary FDA approvals nor was it manufactured in conformity with good manufacturing practice. He also knowingly and willfully made a false statement in a matter, within the jurisdiction of FDA, related to FDA's regulation of the injectable animal drug, "Cal-Plex."

Section 306(a)(2) of the act (21 U.S.C. 335a(a)(2)) mandates debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the act. Under section 306(l)(2) of the act, mandatory debarment applies when an individual is convicted within 5 years preceding the initiation of the agency's action to debar. Section 306(c)(2)(A)(ii) of the act requires that such debarment be permanent.

FDA has made a finding that Mr. Girdhari was convicted of two felonies under Federal law for conduct relating to the regulation of Radix drug products. Mr. Girdhari's first felony conviction under 18 U.S.C. 1001 was for making a false statement to FDA about the manufacture and distribution of the unapproved injectable animal drug, "Cal-Plex." The information he falsified concerns matters that affect FDA's regulatory decisions about drug products. His second felony conviction under section 301(a) of the act was for violations of provisions of the act that prohibit introduction and delivery for introduction into interstate commerce of any drug that is adulterated, a felony conviction under Federal law for conduct relating to the regulation of a drug product under the act.

In a certified letter received by Mr. Girdhari on October 17, 1994, the Interim Deputy Commissioner for Operations of FDA proposed to issue an order under section 306(a)(2) of the act permanently debarring Mr. Girdhari