Date: September 9, 2009.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[30Day–09–09BH]**

### 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) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

Assessing the Safety Culture of Underground Coal Mining—New—National Institute for Occupational Safety and Health, (NIOSH), Centers for Disease Control and Prevention, (CDC).

*Background and Brief Description*

NIOSH, under Public Law 91–596, (Section 20–22, Occupational Safety and Health Act of 1970) has the responsibility to conduct research relating to innovative methods, techniques, and approaches dealing with occupational safety and health problems.

This research relates to occupational safety and health problems in the coal mining industry. In recent years, coal mining safety has attained national attention due to highly publicized disasters. Despite these threats to worker safety and health, the U.S. relies on coal mining to meet its electricity needs. For this reason, the coal mining industry must continue to find ways to protect its workers while maintaining productivity. One way to do so is through improving the safety culture at coal mines. In order to achieve this culture, operators, employees, the inspectorate, etc. must share a fundamental commitment to it as a value. This type of culture is known in other industries as a ''safety culture.'' Safety culture can be defined as the characteristics of the work environment, such as the norms, rules, and common understandings that influence employees' perceptions of the importance that the organization places on safety.

NIOSH proposes an assessment of the current safety culture of underground coal mining in order to identify recommendations for promoting and ensuring the existence of a positive safety culture across the industry. A total of 6 underground coal mines will be studied for this assessment in an attempt to study mines of different characteristics. It is hoped that a small, a medium and a large unionized as well as non-unionized mines will participate. Data will be collected one time at each mine; this is not a longitudinal study. The assessment includes the collection of data using several diagnostic tools: (a) Functional analysis, (b) structured interviews, (c) behavioral observations, and (d) surveys.

It is estimated that across the 6 mines approximately 900 respondents will be surveyed. Similarly the number of interviews will be based upon the number of individuals in the mine population. An exact number of participants is unavailable at this time because not all mine sites have been selected.

The use of multiple methods to assess safety culture is a key aspect to the methodology. After all of the information has been gathered, a variety of statistical and qualitative analyses are conducted on the data to obtain conclusions with respect to the mine's safety culture. The results from these analyses will be presented in a report describing the status of the behaviors important to safety culture at that mine.

This project will provide recommendations for the enactment of new safety practices or the enhancement of existing safety practices across the underground coal mining industry. This final report will present a generalized model of a positive safety culture for underground coal mines that can be applied at individual mines. In addition, all study measures and procedures will be available for mines to use in the future to evaluate their own safety cultures. There is no cost to respondents other than their time. The total estimated annualized burden hours are 480.

ESTIMATED ANNUALIZED BURDEN HOURS

| Phase | Type of respondents | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---|---|---|---|---|
| Year one Survey | Mine Employees | 500 | 1 | 20/60 |
| Year one Interviews | Mine Employees | 100 | 1 | 1 |
| Year two Survey | Mine Employees | 400 | 1 | 20/60 |
| Year two Interviews | Mine Employees | 80 | 1 | 1 |

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–D–0408]**

### Draft Guidance for Industry on Microbiological Data for Systemic Antibacterial Drug Products—Development, Analysis, and Presentation; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Microbiological Data for Systemic Antibacterial Drug Products—Development, Analysis, and Presentation.'' The draft guidance informs industry of FDA's current thinking regarding the types of microbiological studies, assessments, and clinical trials needed to support an investigational new drug application (IND) and a new drug application (NDA) for a systemic antibacterial drug product. Recommendations in this guidance cover microbiological considerations in the three major areas of conducting general nonclinical studies; conducting animal and human studies and clinical trials; and establishing and updating in vitro susceptibility test methods, quality control (QC) parameters, and interpretive criteria. This guidance also recommends the content and format for presentation of microbiological data for antibacterial drug products in the Microbiology subsection of labeling.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 16, 2009.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Fred Marsik, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6108, Silver Spring, MD 20993–0002, 301–796–7956; or

Edward Cox, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6212, Silver Spring, MD 20993–0002, 301–796–1300.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Microbiological Data for Systemic Antibacterial Drug Products—Development, Analysis, and Presentation.'' This guidance provides recommendations on the type of information to provide in submissions to the clinical microbiology section of INDs and NDAs for systemic antibacterial drug products. The in vitro microbiological data and in vivo animal studies (e.g., spectrum of activity in vitro and in appropriate animal models of human disease) support the justification of testing in humans. Sponsors usually submit data from nonclinical investigations to provide proof of concept of clinical activity before commencing human phase 2 studies and clinical trials and to aid in the development of provisional interpretive criteria for use in phase 3 clinical trials. Microbiological data submitted to an NDA will be used to substantiate the microbiological information contained in the labeling.

Specific topics discussed in the guidance include validating in vitro susceptibility testing methods; mechanism of action studies; mechanism of resistance studies; use of animal models; clinical trial protocols; establishment of QC parameters and interpretive criteria; submission and placement of microbiology information in the NDA submission; format and content of the Microbiology subsection of the labeling; and revision of existing susceptibility testing methods, QC parameters, or interpretive criteria.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the microbiological data for systemic antibacterial drug products. 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 statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

(1) The draft guidance provides recommendations on the type of information to include in submissions of the clinical microbiology section of INDs and NDAs for systemic antibacterial drug products. The microbiology section of an NDA is required under 21 CFR 314.50(d)(4) and this information collection is approved under OMB Control Number 0910–0001. For INDs, this information is required under 21 CFR 312.23(a) and approved under OMB Control Number 0910–0014.

(2) The draft guidance also recommends the types of data that should be submitted in a labeling supplement to update the microbiology information in approved labeling if an application holder chooses to update this information without relying on a standard recognized by FDA. The submission of labeling supplements is required under 21 CFR 314.70(b)(2)(v) and 201.56(a)(2) and this information collection is approved under OMB Control Numbers 0910–0001 and 0910–0572, respectively.

(3) Appendix A of the draft guidance describes the content of the Microbiology subsection of labeling. This labeling is covered under 21 CFR 201.57(c)(13)(i) and the information collection is approved under OMB Control Number 0910–0572.

(4) The draft guidance also references the guidance for industry entitled ''Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices'' for updating labeling information. The information collection in this guidance has been approved under OMB Control Number 0910–0638.