

(ivermectin 1.55 percent/praziquantel 7.75 percent) Paste. The application provides for use of an ivermectin and praziquantel oral paste for the control of various species of internal parasites in horses. The NADA is approved as of April 17, 2003, and 21 CFR part 520 is amended by adding new § 520.1198 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning April 17, 2003.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

#### PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.1198 is added to read as follows:

#### § 520.1198 Ivermectin and praziquantel paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.0155 mg (1.55 percent) ivermectin and 0.0775 mg (7.75 percent) praziquantel.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses*—(1) Amount. 200 micrograms (µg) per kilogram (/kg) ivermectin (91 µg per pound (/lb)) and 1 mg/kg praziquantel (454 µg/lb) body weight.

(2) *Indications for use*—For treatment and control of tapeworms *Anoplocephala perfoliata*; large strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*; *Triodontophorus* spp., including *T. brevicauda* and *T. serratus*; and *Craterostomum acuticaudatum*; small strongyles including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae)—*Coronocylus* spp., including *C. coronatus*, *C. labiatus*, and *C. labratus*; *Cyathostomum* spp., including *C. catinatum* and *C. pateratum*; *Cylicocylus* spp., including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*; *Cylicodontophorus* spp.; *Cylicostephanus* spp., including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*; *Petrovinema poculatum*; pinworms (adults and fourth-stage larvae)—*Oxyuris equi*; ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum*; hairworms (adults)—*Trichostrongylus axei*; large-mouth stomach worms (adults)—*Habronema muscae*; bots (oral and gastric stages)—*Gasterophilus* spp., including *G. intestinalis* and *G. nasalis*; lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi*; intestinal threadworms (adults)—*Strongyloides westeri*; summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

Dated: June 20, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

#### 29 CFR Part 1904

[Docket Nos. R-02, R-02A, R-02B]

RIN 1218-AC06

### Occupational Injury and Illness Recording and Reporting Requirements

**AGENCY:** Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

**ACTION:** Final rule.

**SUMMARY:** The Occupational Safety and Health Administration (OSHA) is deleting two provisions of the Occupational Injury and Illness Recording and Reporting Requirements rule published January 19, 2001. These provisions required employers to check the MSD column on the OSHA 300 Log if an employee experienced a work-related musculoskeletal disorder (MSD), and stated that MSDs are not considered privacy concern cases. The effective date of these provisions has been delayed since publication of the Recordkeeping rule in January 2001; consequently, the requirements deleted by this final rule have never been in effect.

**DATES:** The amendments in this rule will become effective on January 1, 2004.

**FOR FURTHER INFORMATION CONTACT:** Steven F. Witt, OSHA Directorate of Standards and Guidance, Room N-3718, Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 693-1950.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On January 19, 2001, OSHA published revisions to its rule on recording and reporting occupational injuries and illnesses (66 FR 5916-6135) to take effect on January 1, 2002. Section 1904.12(a) of that rule, which has never become effective, required an employer to check the MSD column on the OSHA 300 Log if an employee experienced a work-related musculoskeletal disorder (MSD) meeting the MSD definition contained in the regulation. The term MSD was defined in § 1904.12(b) to include disorders of the muscles, nerves, tendons, ligaments, joints, cartilage and spinal discs, except those caused by slips, trips, falls, motor vehicle accidents or other similar accidents.

Section 1904.12 did not establish the criteria for determining which MSD cases were recordable. Rather, the section made clear that MSDs were to be treated like any other injury or illness for purposes of applying the recording criteria and entering the necessary descriptive information about the case on the Log. Section 1904.12(b)(2) provided that

There are no special criteria for determining which musculoskeletal disorders to record. An MSD case is recorded using the same process you would use for any other injury or illness. If a musculoskeletal disorder is work-related, and is a new case, and meets one or more of the general recording criteria, you must record the musculoskeletal disorder.

(66 FR 6129) A table in § 1904.12(b)(2) referred employers to other sections containing the recording criteria: § 1904.5 on work-relatedness, § 1904.6 on new cases, and § 1904.7 on the general recording criteria. Thus, the deletion of § 1904.12 in this final rule does not affect the employer's obligation to record all injuries and illnesses meeting the requirements of §§ 1904.5–1904.7, including those meeting the definition of MSD in the rescinded § 1904.12.

Prior to the January 2001 final rule, OSHA's injury and illness forms did not contain a column specifically for MSD cases. The old 200 Log contained a column for "repeated trauma" cases, which included some disorders affecting musculoskeletal tissues, but also included other conditions, such as occupational hearing loss. In the preamble to the 2001 recordkeeping rule, the Agency concluded that adding a column to the new 300 Log for MSDs was "essential to obtain an accurate picture of the MSD problem in the United States." (66 FR 6030) The preamble noted that determining the number of MSD cases in the past has required close cooperation between OSHA and BLS, and the use of special computer analyses. Use of an MSD column would, in the Agency's view, promote more accurate reporting of MSDs and provide needed information on the overall incidence of MSDs in the workplace. (66 FR 6030) OSHA also stated that the column would provide a useful analytical tool at the establishment level. The preamble states, "The total count of cases in the MSD column will allow employers, employees, authorized representatives, and government representatives to determine, at a glance, what the incidence of these disorders in the establishment is." (66 FR 6030 emphasis added).

On July 3, 2001, OSHA proposed to delay the effective date of § 1904.12 until January 1, 2003. OSHA explained that it was reconsidering the MSD column requirement and definition in light of the Secretary of Labor's decision to develop a comprehensive plan to address ergonomic hazards, and to schedule a series of forums to consider key issues relating to the plan, including the approach to defining ergonomic injuries (66 FR 35113–35115).

After considering the views of interested parties, OSHA published a final rule on October 12, 2001 delaying the effective date of 29 CFR 1904.12 until January 1, 2003. OSHA also added a note to 29 CFR 1904.29(b)(7)(vi) explaining that the second sentence of that section, which states that MSDs are not "privacy concern cases," would not become effective until January 1, 2003. OSHA concluded that delaying the effective date of the MSD definition in § 1904.12 was appropriate because the Secretary was considering a related definitional question in the context of her comprehensive ergonomics plan. The Agency found that it would be premature to implement § 1904.12 before considering the views of business, labor and the public health community on the problem of ergonomic hazards. OSHA also found that it would create confusion and uncertainty to require employers to implement the new definition of MSD contained in § 1904.12 while the Secretary was considering how to define an ergonomic injury under the comprehensive plan (66 FR 52031–52034).

On April 5, 2002, OSHA announced a comprehensive plan to address ergonomic injuries through a combination of industry-targeted guidelines, enforcement measures, workplace outreach, research, and dedicated efforts to protect Hispanic and other immigrant workers. The comprehensive plan did not include a single definition of MSD. In the frequently asked questions (FAQs) issued with the plan, OSHA recognized that "MSD" is a term of art in scientific literature that refers collectively to a group of injuries and illnesses that affect the musculoskeletal system and that there is no single diagnosis for these disorders. The FAQs also indicated that different definitions of MSD might be appropriate depending upon the context in which they are to be used.

On July 1, 2002, OSHA published a **Federal Register** document outlining two further regulatory actions regarding § 1904.12. In Part I of the document, OSHA proposed to delay the effective date of § 1904.12 and the second

sentence of § 1904.29(b)(7)(vi) for an additional year until January 1, 2004. (67 FR 44124–44126) In Part III of the document, OSHA requested comment on issues related to the MSD column and definition. (67 FR 44126–44127)

OSHA noted that a number of participants in the ergonomics forums had argued that the § 1904.12 definition of MSD combines too many disparate types of disorders to be useful. They pointed out that there are at least two distinct categories of disorders covered by the definition; disorders caused by a single event, such as a heavy lift, and disorders caused by repetitive or cumulative events, such as repetitive lifting, typing or assembly line work. To produce more relevant statistics, these participants suggested, OSHA should narrow the definition to focus on a group of disorders having common characteristics. Alternatively, some participants suggested that the MSD definition should be limited in its application to employment conditions involving regular or routine exposure to the activity that resulted in the injury. Other forum participants disagreed, claiming that the existing definition is the most relevant because, among other things, it is often difficult to determine if an MSD was caused by a single event or if a single event was merely the last in a series of events that lead to the injury. (67 FR 44125)

The Agency stated that it was considering whether an MSD column was necessary to produce better statistics. It asked for comment on a number of related issues, including whether "the statistics generated by an additional column [would] be superior to those now generated by the BLS." (67 FR 44127) The Agency also indicated that it was considering a range of options, including deleting § 1904.12 if a column requirement was determined to be unnecessary. The request for comment stated, in relevant part, as follows:

### III. Issues for Public Comment

OSHA invites comment on the following issues:

\* \* \*

**Issue 2.** Is an MSD column needed on the OSHA 300 Log? Should the column be reinstated in § 1904.12 or should § 1904.12 be deleted? Would the statistics generated by an additional column be superior to the statistics now generated by the BLS? Are there other ways to produce statistics on MSDs that do not require revision of the forms? If the column is retained, should it include both injuries and illnesses, or should it be limited to MSD illnesses? Are there other problems associated with an MSD column on the 300 Log? Are there other advantages to the column?

**Issue 3.** If OSHA decides to include a separate column for MSD injuries and illnesses, what definition of MSD should be used? \* \* \*

(67 FR 44126–44127)

On December 17, 2002, OSHA issued a final rule delaying until January 1, 2004 the effective date of the MSD and hearing loss column requirements in §§ 1904.12 and 1904.10, and the statement in § 1904.29(b)(7)(vi) that MSDs are not considered privacy concern cases. (67 FR 77165) OSHA reached no final decision on the need for an MSD column in the December 17 rule, and stated that it would issue a final rule in 2003 resolving the issue. OSHA has now decided to delete the column and associated definition from the Recordkeeping rule.

## II. Discussion

### A. Public Comments on the Need for an MSD Column on the Log

Most parties responding to the July 1, 2002 request for comments opposed the MSD column on the Log. Several commenters argued that the column would not produce useful information. For example, the Society of the Plastics Industry (SPI), asserted that:

As currently used, the term MSD refers to a broad spectrum of physical conditions which may affect any tissue of the musculoskeletal system. The specific diagnosis which this term encompasses can have vastly different characteristics, can be caused by significantly different types of exposures, and can require substantially different prevention measures and treatments. If all cases falling within the multitude of conditions collectively referred to as 'MSDs' are grouped into a single column, and this data is collected through the annual BLS survey, the result is likely to be the projection by BLS of a relatively large and unreliable set of numbers allegedly representing recordable MSDs. The numbers would be meaningless in the sense that they fail to provide OSHA or other interested parties with the information needed to determine the frequency, incident rate, causation or means of preventing any particular condition—e.g., carpal tunnel syndrome, epicondylitis (Ex. 2–29 at 6).

The Synthetic Organic Chemical Manufacturers Association (SOCMA) echoed this concern, stating that “add[ing] a column on the 300 Form will not generate true causal information useful for accident prevention. Knowing that 20%–35% of accidents have a check in the MSD column on the OSHA 300 form is not information useful to companies wishing to improve safety.” Ex. 2–9 at 2.

Other participants argued that § 1904.12 should be deleted because:

- An MSD column was unnecessary, e.g., Exs. 2–7, 2–9, 2–14, 2–21, 2–23, 2–27, 2–30, 3–5, 3–12, 3–16;

- OSHA’s comprehensive ergonomics plan found that no single definition of MSD was appropriate, e.g., Exs. 2–3, 2–12, 2–13, 2–16, 2–28, 2–29, 2–32, 2–35;

- The § 1904.12 MSD definition was inappropriate, e.g., Exs. 2–3, 2–6, 2–7, 2–8, 2–9, 2–12, 2–13, 2–16, 2–23, 2–27, 2–28, 2–29, 2–30, 2–31, 2–32, 2–35, 3–3, 3–14, 3–16;

- The controversy and lack of consensus in the scientific and medical communities on the MSD issue made it premature for OSHA to include a regulatory definition, e.g., Exs. 2–8, 2–12, 2–13, 2–14, 2–31, 2–32, 2–35, 3–17; and

- The MSD column imposes an unnecessary paperwork burden, e.g., Exs. 2–2, 2–5, 2–9, 2–12, 2–21, 2–23.

OSHA also received comments supporting the MSD column on the Log, (See, e.g., Exs. 2–10, 2–11, 2–18, 2–19, 2–20, 2–22, 2–24, 2–25, 2–26, 2–34, 2–35, 2–36, 2–37, 2–39, 3–2, 3–7, 3–9, 3–15). These commenters argued:

- That an MSD column can be used to identify injuries and develop prevention strategies, (See, e.g., Ex. 2–10, 2–11, 2–18, 2–19, 2–20, 2–22, 2–24, 2–25, 2–34, 2–35, 2–36, 2–39, 3–9, 3–15);

- That an MSD column is needed to develop more complete and consistent statistics by BLS, (See, e.g., Ex. 2–11, 2–18, 2–20, 2–24, 2–25, 2–26, 2–35, 2–36, 3–7);

- That an MSD column helps OSHA and NIOSH during workplace interventions, (See, e.g., Ex. 2–20, 2–24, 2–25, 2–26); and

- That the lack of an MSD column may lead to under-recording of MSD injuries, (See, e.g., Ex. 2–25).

According to the AFL–CIO, the MSD column is needed for two reasons; to assist employers, workers and OSHA in identifying and addressing ergonomic hazards in individual workplaces, and to improve the national statistics on MSDs (Ex. 2–24–1). The AFL–CIO argued that the MSD column would serve as a useful tool at the establishment level by providing a “simple, direct way” for employers and OSHA inspectors to identify MSDs, and potentially hazardous jobs, and calculate MSD rates and trends (Ex. 2–24–1, p. 12). The AFL–CIO claimed that the column was needed at the national level to correct what it asserted was a distorted picture of the MSD problem portrayed by current BLS statistics. The AFL–CIO argued that since BLS only collects data on individual injuries and illnesses resulting in days away from work, BLS’s published reports showing

a decline in MSD incidence rates since 1992 understate the seriousness of the problem posed by these disorders (Ex. 2–24–1, p. 13).

### B. OSHA’s Determination That an MSD Column Is Unnecessary

OSHA has carefully reviewed the determination made in the January 19, 2001 rule and the record supporting that determination, as well as the evidence submitted by the participants in the ergonomics forums and the parties responding to the July 2002 request for comment on the need for an MSD column. The Agency has determined that this record does not support the column requirement. The principal justifications advanced for the column are that it would be a useful tool in analyzing and addressing ergonomic hazards in individual workplaces and that it would yield more accurate national statistics on ergonomic injuries. As discussed below, neither of these justifications is persuasive.

The MSD column would not be a useful tool in addressing MSDs at the establishment level for two reasons. First, because the column would show only the total number of MSDs that occurred in an establishment and nothing about the nature or cause of these disorders, it would be of very little practical use in devising abatement methods for ergonomic hazards. Second, to the extent that employers and workers believe that the total count of MSD cases is relevant in an establishment, the number is easily obtainable without the column requirement.

The January 2001 preamble states that the MSD column would be useful because it would enable employers and others to determine at a glance the total number of these disorders that had occurred. However, the total number, standing alone, tells nothing about the specific types of disorders that may be involved. The MSD definition in § 1904.12 encompasses a broad range of health conditions from back injuries to carpal tunnel syndrome. Thus, the total MSD count in an establishment could include a number of disparate disorders that have little in common. More importantly, the total number of cases tells nothing about the possible causes and prevention of ergonomic hazards. Simply knowing that a certain number of MSD cases have occurred does not permit one to determine which jobs or working conditions pose ergonomic hazards and how they may be abated.

To effectively analyze and address ergonomic injuries that are occurring in workplaces, employers and others must be able to link specific types of injuries

to specific characteristics of jobs or working conditions. This requires evaluation of each individual case to determine the part of the body affected, the nature of the job performed by the injured employee and other relevant data. Such information is currently available in the case-description section of the 300 Log and in the 301 Incident Report. Evaluation of these case-entry data, particularly the job title and the description of the injury and affected body part contained in Columns C and F on the 300 Log, will enable employers, workers and OSHA to identify specific types of MSDs, to link specific MSD injuries to specific ergonomic risk factors, and to identify trends in certain jobs or work practices over time.

The MSD column would not assist with the kind of detailed analysis necessary to effectively abate MSDs at the establishment level. Conscientious employers, employees and authorized representatives who wish to address MSDs in their workplaces will do so, as they have in the past, by examining the entire Log, whether or not an MSD column is implemented. Some employers and others may wish to use the § 1904.12 definition of MSD as part of their comprehensive records analysis or they may wish to use a different definition more suited to their specific working conditions. For example, nursing home employers may wish to focus particularly on back cases in analyzing the effectiveness of patient lifting and repositioning abatement measures. On the other hand, employers and others who do not wish to perform a comprehensive analysis would not be able to use an MSD column as a substitute for the analysis.

To the extent that the aggregate total of MSD cases is of some relevance, the number can easily be determined without a column. Based on the description-of-injury information in column F of the Log, one can very quickly identify which cases are MSDs under the § 1904.12 definition, or an alternative definition such as the one in OSHA's meatpacking guidelines. The MSD column is simply not necessary for this purpose. For these reasons, OSHA concludes that the MSD column would not be a useful tool at the establishment level.

A related point argued by some is that an MSD column is needed to ensure effective enforcement of the general duty clause. However, the column has never been in effect and has not been a factor in enforcement of the clause. It is difficult to see the utility of simply checking an MSD column given the detailed nature of the information needed by OSHA to sustain a general

duty clause citation. The case description data in the 300 and 301 forms is available to assist OSHA in its inspection activities. This information permits a more comprehensive understanding of MSDs in workplaces than would a single aggregate statistic produced by a column. Accordingly, there is no need for an MSD column on the Log for enforcement purposes.

The other justification cited for the MSD column is that it is necessary to improve the accuracy and usefulness of the national injury and illness statistics. However, OSHA concludes that MSD column would not materially improve the national statistics on MSDs. The national statistics already include comprehensive information about MSDs that result in days away from work, including the total number and incidence rate of these disorders. As to other MSDs, the MSD column would allow the Bureau of Labor Statistics (BLS) to calculate the total number of these cases, but not to analyze their characteristics in any way. OSHA does not believe that a new statistic on total MSDs would be useful without the ability to assess the specific characteristics of these disorders. To obtain additional data necessary to allow BLS to assess the characteristics of MSDs that do not require days away from work would require significant changes to the BLS survey system not contemplated in the proposed recordkeeping rule and not requested by any party.

#### Overview of the BLS Statistical Program

BLS is responsible for producing the national injury and illness statistics. BLS currently publishes two categories of statistics on non-fatal injuries and illnesses. One category consists of detailed information about injuries and illnesses that require days away from work to recuperate; the other category consists of aggregate totals for all types of injuries and illnesses combined.

The first category of statistics, called case characteristics, is derived from a survey eliciting information from participating employers on a sample of injuries and illnesses resulting in days away from work. The survey provides detailed information about the specific characteristics of these cases, including the employee's age, sex, occupation and length of service; the employer's industry classification; the number of days away from work that were required; the part of the body affected; the source of injury (e.g., bodily motion or position, machinery, fire, toxic substance) and the causal event or exposure (e.g., overexertion, repetitive motion, fall, explosion).

BLS produces information on MSDs from those days away from work cases for which characteristics data are collected. BLS categorizes a case as an MSD using information on the nature of the injury and illness and the event or exposure leading to the injury or illness, as reported by the employer. Cases reported as MSDs by BLS include those in which the nature of the injury is a sprain, strain, tear, soreness, hernia, carpal tunnel syndrome or other similar type of injury to the soft tissue structures, and in which the causal event is bodily movement, such as bending, climbing, reaching, twisting, overexertion, or repetition. See BLS report *Lost-worktime Injuries and Illnesses: Characteristics and Resulting Time Away From Work 2000*, available on the BLS Internet site ([www.bls.gov](http://www.bls.gov)).

The BLS case characteristic data permit detailed analysis of different types of MSDs by employee age and sex, occupation, industry sector, severity of disorder, type of causal event, type of bodily motion and other relevant characteristics. As a result, the BLS data can be highly useful in identifying the most serious MSDs and the conditions leading to them, and in pinpointing high-risk industries and occupations. For example, the BLS Supplemental Tables for calendar year 2000 contain a detailed breakdown of lost-worktime MSDs by type, severity, source of injury, event or exposure, and other characteristics. The breakdown also presents the aggregate number of lost-worktime MSDs that occurred by major industry sector. See *Case and Demographic Characteristics for Work-related Injuries and Illnesses Involving Days Away From Work, Supplemental Tables for 2000*, Table 11. Additional Tables for 2000 contain detailed breakdowns of specific types of MSDs, such as carpal tunnel syndrome, tendonitis and repetitive motion injuries. See *Id.*, Tables 3 and 9.

The case characteristic data are also helpful in identifying significant information on the incidence of specific disorders. For example, in 2000, the latest year for which case characteristic data are available, the BLS statistics show that carpal tunnel syndrome accounted for the highest median number of days away from work of any disabling injury or illness, that repetitive motion and typing resulted in the longest absences from work among the leading events and exposures, and that truck drivers, nursing aides and non-construction laborers were the occupations with the greatest numbers of aggregated MSDs, accounting for one out of five of these disorders. See the BLS report *Lost-Worktime Injuries and*

*Illnesses: Characteristics and Resulting Time Away From Work, 2000* (April 10, 2002), available on the BLS Internet site.

A second category of statistics is concerned with the total number and incidence rate of non-fatal cases of all types. Statistics in this series indicate, for each sector of private industry, the total number of non-fatal injuries and illnesses reported as well as the number of these cases with lost-workdays and the number of cases without lost-workdays. This series also includes the incidence rate of non-fatal injuries and illnesses by industry calculated as the number of cases per 100 full time employees. See the BLS report *Workplace Injuries and Illnesses in 2000* (December 18, 2001).<sup>1</sup> Together these two types of statistics—case characteristic data and overall incidence data—present a wealth of information about occupational injuries and illnesses across the nation.

#### Why the MSD Column Would Not Significantly Improve the BLS Statistics

If the MSD column were implemented, employers participating in the BLS survey would report annually the total number of MSD cases checked on the Log. This information would enable BLS to publish the total number and incidence rates of MSDs of all types. Thus, the statistical tables depicting the total number and incidence rates of non-fatal injuries and illnesses by industry would include an additional column for total MSD cases. (See, e.g., *Workplace Injuries and Illnesses in 2000*, Tables S14 and S16)

These new statistics would add only marginally to the information currently available. As described above, the BLS case characteristic data already present a comprehensive picture of the most severe MSDs, including separate statistics on the total number and incidence rate of these disorders. Accordingly, the MSD column would add minimally to the national statistics on MSDs that resulted in days away from work.

The new data would be relevant primarily for the purpose of estimating the number of MSDs that do not result in days away from work. The number of these MSDs could be approximated by subtracting the number of days away from work MSD cases reported by BLS from the total number of MSDs of all types produced by the column. However this estimate would have limited utility

because the absence of case characteristic data for cases that do not result in days away from work MSDs precludes analysis of them.

As noted above, the BLS survey elicits descriptive information only on injuries and illnesses, including MSDs, resulting in days away from work. The BLS database of case-characteristics has never included information on or analyses of cases that do not result in days away from work. Accordingly, BLS cannot analyze the characteristics of these injuries and illnesses as it can days away from work cases. Adding an MSD column to the Log would not change the basic structure of the survey, and would not produce any additional descriptive data on the less severe cases. Significant changes in the survey itself would be required before BLS could collect this type of data.

Because an MSD column would not enable BLS to collect case characteristic data on all MSDs, any new statistic reporting the aggregate total number of such cases would be difficult to interpret. There would be no way to distinguish among different types of these disorders, determine possible causal factors, evaluate demographics, or perform the other analyses. OSHA believes that total number of MSDs, standing alone, would not be useful without the ability to analyze the underlying data.

Having a column requirement might be warranted if a specific injury or illness was substantially misrepresented in the BLS statistics for cases with days away from work. For example, OSHA recently found that the estimate of days away from work occupational hearing loss cases, which totaled only 316 cases in the year 2000, probably represents only a tiny fraction of the total hearing loss cases in the Nation because workers commonly suffer hearing loss and never require a day away from work. (See, e.g., 67 FR 77168 explaining the need for a hearing loss column on the Log.) In the 2001 Recordkeeping rule, OSHA stated that it believed that many cases of hearing loss, probably numbering in the thousands, do not result in days away from work and are therefore not represented in the BLS statistics. (66 FR 6005). Because the BLS statistics on hearing loss represented only a minor fraction of the hearing loss experienced by workers, OSHA believed that a column was necessary to obtain useful data on hearing loss cases. In contrast, BLS produces a wealth of useful information about MSDs. The BLS statistics for the year 2000 included over 577,800 MSDs with days away from work, accounting for more than eleven percent of all private sector

occupational injuries and illnesses. (See *Lost-worktime Injuries and Illnesses: Characteristics and Resulting Time Away From Work, 2000*, page 3.) This is a large number of cases, representing those MSDs with the most serious outcomes. Moreover, this total figure can be broken down and analyzed in many different ways using BLS's case characteristics. Thus, there is no need for a column to obtain useful data for MSDs, as there was for hearing loss cases.

OSHA does not believe that altering the definition used to trigger the column requirement would produce more useful data. As some, including the AFL-CIO, have observed, the § 1904.12 definition is similar in some ways to definitions OSHA has used in the past, and that BLS and other agencies now use. OSHA believes that this definition can be useful for some purposes. Different definitions might also be appropriate in some contexts. For example, in evaluating the effectiveness of an ergonomics program targeted to certain specific risk factors, it might be useful to define MSDs to include injuries likely to be caused by exposure to such factors. This is very different from using an MSD column to generate a single aggregate statistic. Regardless of how MSDs are defined for purposes of the OSHA recordkeeping rule, a column requirement would produce only an aggregate total of cases that could not be further analyzed for significance. No such statistic would be useful without a means of understanding and interpreting it.

Finally OSHA has considered whether the BLS survey should be modified to gather case-characteristic data for all recordable MSDs, regardless of type or severity. The Agency believes that it is reasonable for BLS to collect detailed characteristic data only for injuries and illnesses that result in days away from work at this time. BLS cannot collect comprehensive data on every aspect of every injury or illness. The current survey was designed and implemented with the support and assistance of the safety and health community and the 40 participating States to capture detailed information on the most severe cases. (See *BLS Handbook of Methods*, Ch. 9, Occupational Safety and Health Statistics) The statistical system, of which the survey is a part, fulfills the statutory requirement to "compile accurate statistics on work injuries and illnesses," 29 U.S.C. 673, by producing data on the overall number and incidence rate of injuries and illnesses, by industry, and by providing detailed statistics on case characteristics of

<sup>1</sup> The reports *Lost-worktime Injuries and Illnesses: Characteristics and Resulting Time Away from Work, 2000* and *Workplace Injuries and Illnesses in 2000*, were two of three reports issued by BLS for calendar year 2000. In August 2001, BLS issued a report covering work-related fatalities.

occupational injuries and illnesses, that result in days away from work, including MSDs, to assist in the understanding and prevention of these disabling cases. The system is not currently designed to gather separate statistics on the incidence rates of specific injuries or illnesses.

Nothing in the record demonstrates that BLS should treat MSDs differently from other injuries and illnesses by publishing separate statistics on all recordable cases of these disorders. OSHA does not believe that MSDs are fundamentally different, for statistical purposes, from bruises, cuts, lacerations, burns and other common injuries which may or may not result in days away from work depending on severity. As discussed above, the national statistics present a detailed picture of the MSD problem on a variety of levels. These data are both accurate and useful. Accordingly, OSHA concludes that there is no justification for the MSD column on the Log.

#### Consultation With NACE

While the Agency concludes that the MSD column on the Log would not produce significantly more accurate or useful statistics, it is committed to exploring other means of improving the information available on MSDs and effectively utilizing this information to reduce ergonomic-related injuries and illnesses in the workplace. As part of the comprehensive approach for addressing MSD hazards, the Department has created the National Advisory Committee on Ergonomics (NACE) to advise the Assistant Secretary of Labor for Occupational Safety and Health on ergonomic guidelines, research, and outreach assistance. The Agency has indicated that it will seek advice from NACE in the following areas: (1) The development of various industry or task-specific guidelines; (2) identification of gaps in the existing research base related to applying ergonomic principles to the workplace; (3) current and projected research needs and efforts, including information provided by NIOSH; (4) methods of providing outreach and assistance that will communicate the value of ergonomics to employers and employees, and (5) ways to increase communication among stakeholders on the issue of ergonomics. As part of this effort, the Agency intends to seek input from NACE on how to characterize the variety of ergonomic-related injuries in the workplace in ways that will be most useful in helping employers and others to solve ergonomic problems. NACE's expertise will also be useful in advising the Agency on ways in which statistics

on these injuries can be used effectively in developing guidelines and in providing outreach and assistance on ergonomics to employers, employees and stakeholders.

#### *C. Deletion of 29 CFR 1904.12 and Related Provisions*

Having concluded that an MSD column on the Log is unnecessary, OSHA believes that section 1904.12 should be deleted. The sole purpose of that section was to establish the requirement for employers to check the MSD column for cases meeting the definition of MSD. In view of this determination, it is not necessary to consider whether the definition of MSD in § 1904.12 would be appropriate if a column were needed, or whether alternative definitions would be appropriate. The deletion of § 1904.12 relieves employers from the legal requirement to check the column; however, it has no effect on their obligation to record all cases meeting the requirements of §§ 1904.4–1904.7. In a related matter, some of the privacy provisions of Part 1904 relied upon the MSD definition from § 1904.12. Specifically, paragraph 1904.29(b)(7)(vi) of the rule states that employers must consider an illness case to be a privacy concern case, and withhold the employee's name from the forms, if the employee independently and voluntarily requests that his or her name not be entered on the Log. The second sentence of the paragraph states “[m]usculoskeletal disorders (MSDs) are not considered privacy concern cases.” Because § 1904.12 is being deleted, there is no basis to implement the requirement in § 1904.29(b)(7)(vi). Moreover, there was no explanation for the special privacy treatment accorded MSDs in the preamble to the 2001 rule. Accordingly, OSHA is deleting the MSD requirement in section 1904.29(b)(7)(vi) stating that MSD injuries and illnesses are not to be considered privacy concern cases. These cases are covered by the general rule on privacy cases. Therefore, when the employer has categorized the case as an occupational illness, and the employee independently and voluntarily requests that his or her name not be entered on the OSHA 300 Log, the case will be considered a privacy concern case.

#### Paperwork Reduction Act

This final rule deletes requirements contained in OSHA's January 19, 2001 final recordkeeping rule but never implemented. Therefore, this rule continues OSHA's current policies on recording of MSDs, and protecting employee privacy, resulting in no

change in actual paperwork burden compared with current practice. While this final rule results in a minor saving in burden that would have been imposed, OSHA has not attempted to estimate the saving because the January 2001 rule contained no separate estimate of the burden associated with §§ 1904.12 and 1904.29(b)(7)(vi).

#### Regulatory Flexibility Certification

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601), the Assistant Secretary certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The rule deletes requirements that have not become effective, and adds no new requirements. The rule will impose no costs on the regulated public.

#### State Plans

The 26 States and territories with their own OSHA-approved occupational safety and health plans must adopt a comparable regulation within six months of the publication date of this final regulation. These states and territories are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Connecticut, New Jersey, and New York have OSHA approved State Plans that apply to state and local government employees only.

#### Executive Order

This document has been deemed significant under Executive Order 12866 and has been reviewed by OMB.

#### Authority

This document was prepared under the direction of John Henshaw, Assistant Secretary for Occupational Safety and Health. It is issued under Section 8 of the Occupational Safety and Health Act (29 U.S.C. 657) and 5 U.S.C. 553.

Signed at Washington, DC this 25 day of June, 2003.

**John L. Henshaw,**  
*Assistant Secretary of Labor.*

■ For the reasons stated in the preamble, OSHA hereby amends 29 CFR part 1904 as set forth below:

#### PART 1904—[AMENDED]

■ 1. The authority citation for part 1904 continues to read as follows:

**Authority:** 29 U.S.C. 657, 658, 660, 666, 669, 673, Secretary of Labor's Order No. 3–2000 (65 FR 50017), and 5 U.S.C. 533.

**§ 1904.12 [Removed]**

- 2. Remove § 1904.12.

**§ 1904.26 [Amended]**

- 3. Revise § 1904.29(b)(7)(vi) to read as follows:

**§ 1904.29 Forms.**

\* \* \* \* \*

(b) \* \* \*

(7) \* \* \*

(vi) Other illnesses, if the employee voluntarily requests that his or her name not be entered on the log.

\* \* \* \* \*

[FR Doc. 03-16482 Filed 6-27-03; 8:45 am]

BILLING CODE 4510-26-P

**DEPARTMENT OF LABOR****Mine Safety and Health Administration****30 CFR Part 3****Office of Management and Budget (OMB) Control Numbers under the Paperwork Reduction Act**

**AGENCY:** Mine Safety and Health Administration (MSHA), Labor.

**ACTION:** Technical amendment.

**SUMMARY:** This technical amendment revises title 30 of the Code of Federal Regulations (30 CFR) to update the display of Office of Management and Budget (OMB) control numbers for MSHA's standards and regulations. This display assists the public search for current information on OMB control numbers for the information collection, recordkeeping, and reporting requirements approved by OMB under the Paperwork Reduction Act of 1995 (PRA 95).

**EFFECTIVE DATE:** June 30, 2003.

**FOR FURTHER INFORMATION CONTACT:** Marvin W. Nichols, Director; Office of Standards, Regulations, and Variances, MSHA; Phone: 202-693-9440; FAX: 202-693-9441; E-mail: [nichols-marvin@msha.gov](mailto:nichols-marvin@msha.gov).

**SUPPLEMENTARY INFORMATION:** We (MSHA) first consolidated our listing of OMB control numbers in a final rule published on June 29, 1995 (60 FR 33719). This action codified the OMB control numbers for our standards and regulations in one location to assist the public in quickly determining whether a specific information collection requirement was approved by OMB. Table 1 in 30 CFR 3.1 displays the OMB control number for each section containing a requirement for the collection, reporting, recordkeeping, or dissemination of information. This display fulfills the requirements of 44

U.S.C. 3507(f) of PRA 95 which prohibits an agency from engaging in a collection of information without displaying its OMB control number. Under PRA 95, a person is not required to respond to a collection of information if a valid OMB control number is not displayed.

This revision updates our current display of OMB control numbers to include new control numbers approved by OMB for regulations completed since the last update and any changes made through the renewal of previously issued OMB control numbers. There are no substantive changes or renewals made to information collection requirements by this technical amendment.

Information collection requirements go through the public review process as part of the rule to which they apply. Likewise, the renewal of an OMB control number also requires public review. As a result, we find that there is "good cause" under 5 U.S.C. 553(b)(B) of the Administrative Procedure Act (APA) to issue this technical amendment to Table 1 in 30 CFR part 3 without prior public notice and comment.

We also determined that there is no need to delay the effective date. The technical amendment contains no new requirements for which the public would need time, beyond that provided for in the regulation itself, to plan compliance. We find, therefore, there is "good cause" to except this action from the 30-day delayed effective date requirement under 5 U.S.C. 553(b)(B) of the Administrative Procedure Act.

**List of Subjects in 30 CFR Part 3**

Mine safety and health, Reporting and recordkeeping requirements.

Dated: June 24, 2003.

**Dave D. Lauriski,**

*Assistant Secretary of Labor for Mine Safety and Health.*

- Accordingly, under the authority of 30 U.S.C. 957, chapter I of title 30, Code of Federal Regulations is amended as set forth below.

**PART 3—[AMENDED]**

- 1. The authority for part 3 continues to read as follows:

**Authority:** 30 U.S.C. 957; 44 U.S.C. 3501-3520.

- 2. Amend section 3.1 by revising Table 1 to read as follows:

\* \* \* \* \*

TABLE 1.—OMB CONTROL NUMBERS

30 CFR Citation	OMB Control No.
<b>Subchapter B—Testing, Evaluation, and Approval of Mining Products</b>	
7.3 .....	1219-0100
7.4 .....	1219-0100
7.6 .....	1219-0100
7.7 .....	1219-0100
7.23 .....	1219-0100
7.27 .....	1219-0100
7.28 .....	1219-0100
7.29 .....	1219-0100
7.43 .....	1219-0100
7.46 .....	1219-0100
7.47 .....	1219-0100
7.48 .....	1219-0100
7.49 .....	1219-0100
7.51 .....	1219-0100
7.63 .....	1219-0100
7.69 .....	1219-0100
7.71 .....	1219-0100
7.83 .....	1219-0119
7.90 .....	1219-0119
7.97 .....	1219-0119
7.105 .....	1219-0119
7.303 .....	1219-0100
7.306 .....	1219-0100
7.309 .....	1219-0100
7.311 .....	1219-0100
7.403 .....	1219-0100
7.407 .....	1219-0100
7.408 .....	1219-0100
7.409 .....	1219-0100
15.4 .....	1219-0066
15.8 .....	1219-0066
18.6 .....	1219-0066
18.15 .....	1219-0066
18.81 .....	1219-0066
18.82 .....	1219-0066
18.93 .....	1219-0066
18.94 .....	1219-0066
19.3 .....	1219-0066
19.13 .....	1219-0066
20.3 .....	1219-0066
20.14 .....	1219-0066
22.4 .....	1219-0066
22.11 .....	1219-0066
23.3 .....	1219-0066
23.14 .....	1219-0066
27.4 .....	1219-0066
27.6 .....	1219-0066
27.11 .....	1219-0066
28.10 .....	1219-0066
28.25 .....	1219-0066
28.30 .....	1219-0066
28.31 .....	1219-0066
33.6 .....	1219-0066
33.12 .....	1219-0066
35.6 .....	1219-0066
35.12 .....	1219-0066
36.6 .....	1219-0066
36.12 .....	1219-0066

**Subchapter G—Filing and Other Administrative Requirements**

40.3 .....	1219-0042
40.4 .....	1219-0042
40.5 .....	1219-0042
41.10 .....	1219-0008
41.11 .....	1219-0008
41.12 .....	1219-0008
41.20 .....	1219-0008