

or function of the body, and resolved the tension by requiring the disclaimer. Many comments also argued generally that DSHEA was intended to promote the free-flow of truthful information about dietary supplements, and that prohibiting implied disease claims is contrary to this legislative goal.

FDA had proposed to treat both express and implied claims as disease claims on two grounds. First, the agency has always exercised authority over both express and implied claims under section 201(g)(1)(B) of the act (21 U.S.C. 321(g)(1)(B)), and believed that Congress would have explicitly authorized implied claims if it intended to change the agency's longstanding interpretation of the statute. The sections of DSHEA cited by the comments do not contain such an express authorization. Second, FDA believed that most disease treatment or prevention claims, including claims about serious and life-threatening diseases, can be described in a manner that will be easily understood by consumers without express reference to the name of the disease (e.g., "shrinks tumors of the lung"). If dietary supplements were permitted to make implied disease claims, the burden would be on consumers to evaluate the validity of claims about dietary supplements marketed for serious and life-threatening diseases. In addition, dietary supplements could be given an unfair advantage over prescription and over-the-counter drugs in the marketplace that are required to establish their safety and effectiveness for disease treatment and prevention.

In the proposed rule, FDA asked for comment on a specific type of implied disease claim: A claim that a dietary supplement prevents or treats abnormal or unhealthy conditions or clinical measurements that are not themselves diseases but are markers of, or risk factors for, diseases, e.g., "lowers cholesterol." FDA proposed to treat such claims as disease claims, but to permit claims that a product maintains healthy function, e.g., "helps maintain a healthy cholesterol level." Most of the comments argued that consumers do not perceive a distinction between claims that a product treats or prevents abnormal function, and claims that the product maintains healthy function. Comments from dietary supplement manufacturers and some consumer groups argued that both types of claims should be permitted, while comments from health professional groups, groups devoted to specific diseases, and other consumer groups tended to argue that neither type of claim should be permitted.

FDA seeks further input on whether dietary supplements should be permitted to carry implied disease claims without prior review, either as health claims or as drug claims. To help focus comments on this issue for the public meeting, the agency seeks input on the following questions: (1) If such claims should be permitted, how should FDA correctly draw the line between what constitutes a prohibited express claim and what constitutes a permitted implied claim? (2) If such claims should be permitted, what are representative examples of the types of implied disease claims that should be permitted without prior review? (3) Are the examples mentioned in this notice appropriate structure/function claims? (4) Is a claim that a product "maintains healthy function" an implied disease claim in all cases? If not, under what circumstances is such a claim not an implied disease claim?

### III. Registration and Requests to Make Oral Presentations

If you would like to attend the meeting, you must register with the contact person (address above) by July 16, 1999, by providing your name, title, business affiliation, address, telephone, and fax number. To expedite processing, registration information may also be faxed to 301-594-6777. If you need special accommodations due to disability, please inform the contact person when you register.

FDA intends to invite representatives from industry, health professional groups, and consumer groups to participate in panel discussions on the three issues discussed previously during the first portion of the meeting. Presentations by members of the public will be permitted during the second portion of the meeting, as time permits. If, in addition to attending, you wish to make an oral presentation during the meeting, when you register to attend you must so inform the contact person and submit: (1) A brief written statement of the general nature of the arguments you wish to present, (2) the names and addresses of the persons who will give the presentation, and (3) an indication of the approximate time that you request to make your presentation. Depending upon the number of people who register to make presentations, we may have to limit the time allotted for each presentation. We anticipate that, if time permits, those attending the meeting will have the opportunity to ask questions during the meeting.

### IV. Comments

Interested persons may, on or before August 4, 1999, submit written

comments to the Dockets Management Branch (address above). You may also send comments to the Dockets Management Branch via e-mail to "FDADockets@oc.fda.gov". You should annotate and organize your comments to identify the specific issues to which they refer. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document, except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### V. Transcripts

You may request transcripts of the meeting in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. You may also examine the transcript of the meeting at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Website "http://www.fda.gov".

Dated: July 2, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning and Legislation.*

[FR Doc. 99-17424 Filed 7-6-99; 12:26 pm]

BILLING CODE 4160-01-F

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

#### 30 CFR Parts 57, 72 and 75

RIN 1219-AA74; 1219-AB11

#### Diesel Particulate Matter Exposure of Underground Coal and Metal and Nonmetal Miners

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

**ACTION:** Proposed rules; corrections.

**SUMMARY:** This document corrects errors in the preamble discussions to the proposed rule on diesel particulate matter exposure of underground coal miners, and the proposed rule on diesel particulate matter exposure of underground metal and nonmetal miners. Specifically, this document corrects errors in the Diesel Emission Control Estimator formula in the proposed Appendix to Part V of both preambles; and corrects certain titles in proposed Figures V-1 through V-5 of

the metal and nonmetal preamble, and proposed Figure V-5 of the coal preamble.

**DATES:** Written comments on these clarifications and corrections must be submitted on or before July 26, 1999.

**ADDRESSES:** You may use mail, facsimile (fax), or electronic mail to send your comments to MSHA. Clearly identify comments as such and send them—

(1) By mail to Carol J. Jones, Acting Director, Office of Standards, Regulations, and Variances, MSHA, 4015 Wilson Boulevard, Room 631, Arlington, VA 22203;

(2) By fax to MSHA, Office of Standards, Regulations, and Variances, 703-235-5551; or

(3) By electronic mail to [comments@msha.gov](mailto:comments@msha.gov).

**FOR FURTHER INFORMATION CONTACT:** Carol J. Jones, Acting Director; Office of Standards, Regulations, and Variances; MSHA; 703-235-1910.

**SUPPLEMENTARY INFORMATION:** On April 9, 1998 (63 FR 17492), MSHA published a proposed rule addressing diesel particulate matter exposure of underground coal miners. On October 29, 1998 (63 FR 58104), the agency published a proposed rule addressing diesel particulate matter exposure of underground metal and nonmetal miners. These proposals seek to reduce the risks to underground coal and metal and nonmetal miners, respectively, of serious health hazards associated with exposure to high concentrations of diesel particulate matter (dpm). DPM is a very small particle in diesel exhaust. Underground miners are exposed to far higher concentrations of this fine particulate than any other group of workers.

After publication of both proposed rules, MSHA realized that the Diesel Emission Control Estimator formula in Appendix to Part V: Diesel Emission Control Estimator was incorrect. The formula did not contain the unit conversion factors of 60 minutes/hour and 1000 µg/mg. Also, the formula did not contain the "Ts" unit factor, which represents the total shift length, hours. However, the spreadsheet supplied by MSHA performs the calculations correctly because it contains these units.

This document corrects these errors by including the conversion factors, and the "Ts" unit in the Diesel Emission Control Estimator formula. Additionally, the Agency is taking this opportunity to correct certain titles in proposed Figures V-1 through V-5 of the metal and nonmetal preamble, and proposed Figure V-5 of the coal preamble. These titles are being corrected because the specific units of

measurement are misstated. Below are these corrections.

**I. Corrections to Proposed Rule on Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners (63 FR 58104)**

[Figure V-1]:

1. On page 58198, Figure V-1, section 1, line 1, "MEASURED OR ESTIMATED IN MINE DP EXPOSURE (µg/m<sup>3</sup>)" should read "MEASURED OR ESTIMATED DPM CONCENTRATION (µg/m<sup>3</sup>)".

2. On page 58198, Figure V-1, section 2, line 18, "AVERAGE TOTAL SHIFT PARTICULATE OUTPUT (gm)" should read "AVERAGE, TOTAL SHIFT, ENGINE EMISSION RATE (gm/hp-hr)".

[Figure V-2]:

1. On page 58199, Figure V-2, section 1, line 1, "MEASURED OR ESTIMATED IN MINE DP EXPOSURE (µg/m<sup>3</sup>)" should read "MEASURED OR ESTIMATED DPM CONCENTRATION (µg/m<sup>3</sup>)".

2. On page 58199, Figure V-2, section 2, line 18, "AVERAGE TOTAL SHIFT PARTICULATE OUTPUT (gm)" should read "AVERAGE, TOTAL SHIFT, ENGINE EMISSION RATE (gm/hp-hr)".

[Figure V-3]:

1. On page 58200, Figure V-3, section 1, line 1, "MEASURED OR ESTIMATED IN MINE DP EXPOSURE (µg/m<sup>3</sup>)" should read "MEASURED OR ESTIMATED DPM CONCENTRATION (µg/m<sup>3</sup>)".

2. On page 58200, Figure V-3, section 2, line 18, "AVERAGE TOTAL SHIFT PARTICULATE OUTPUT (gm)" should read "AVERAGE, TOTAL SHIFT, ENGINE EMISSION RATE (gm/hp-hr)".

[Figure V-4]:

1. On page 58201, Figure V-4, section 1, line 1, "MEASURED OR ESTIMATED IN MINE DP EXPOSURE (µg/m<sup>3</sup>)" should read "MEASURED OR ESTIMATED DPM CONCENTRATION (µg/m<sup>3</sup>)".

2. On page 58201, Figure V-4, section 2, line 21, "AVERAGE TOTAL SHIFT PARTICULATE OUTPUT (gm)" should read "AVERAGE, TOTAL SHIFT, ENGINE EMISSION RATE (gm/hp-hr)".

[Figure V-5]:

1. On page 58205, Figure V-5, section 1, line 1, "MEASURED OR ESTIMATED IN MINE DP EXPOSURE (µg/m<sup>3</sup>)" should read "MEASURED OR ESTIMATED DPM CONCENTRATION (µg/m<sup>3</sup>)".

2. On page 58205, Figure V-5, section 2, line 18, "AVERAGE TOTAL SHIFT PARTICULATE OUTPUT (gm)" should read "AVERAGE, TOTAL SHIFT, ENGINE EMISSION RATE (gm/hp-hr)".

3. On page 58205, Figure V-5, section 3, line 4, Column B, "73 cfm/hp" should read "173 cfm/hp".

4. On page 58206, second column, line 3, " $E(a) = (DPM(m) - I) \times (Q(I) / 35200) / [Sum(Hp(I) \times To(I))]$ " should read " $E(a) = (DPM(m) - I) \times Ts \times Q(I) \times 1.7 / [10^6 \times Sum(Hp(I) \times To(I))]$ ".

5. On page 58206, second column, line 12, "To(I) = Individual engine operating times, hours" should read "Ts = Total shift length, hours".

6. On page 58206, second column, line 14, insert the following before beginning of paragraph: "To(I) = Individual engine operating times, hr; '1.7 = The metric conversion factor that converts cfm to m<sup>3</sup>/hr, 1.7'; '10<sup>6</sup> = The conversion factor that converts gm to µg".

7. On page 58206, third column, line 9, " $DPM(a) = \{ [Sum(E(I) \times Hp(I) \times To(I)) \times 35,300 / Q(I)] + I \} \times [Ts / 8]$ " should read " $DPM(a) = [E(a) \times Sum(Hp(I) \times 10^6 / 1.7 \times Q(I)) + I] \times Ts / 8$ ".

8. On page 58206, third column, line 12, "35,300 is a metric conversion factor" should be deleted.

9. On page 58206, third column, line 16, "E(I) = Individual engine emission rates, gm/hp-hr" should read "E(a) = is the quantity calculated for section 2, Column B, the average engine emission rate, gm/hp-hr".

10. On page 58206, third column, line 19, "To(I) = Operating time hours" should be deleted.

11. On page 58206, third column, line 23, insert the following before the beginning of paragraph: "1.7 = The metric conversion factor that converts cfm to m<sup>3</sup>/hr, 1.7"; "10<sup>6</sup> = The conversion factor that converts gm to µg".

12. On page 58207, first column, line 71, " $DPM(c) = \{ Sum[E(I) \times Hp(I) \times To(I) \times (35300 / Q(I)) \times (1 - R(o)) \times (1 - R(f)) \times (1 - R(e))] \times [Q(I) / Q(f)] \} + I$ " should read " $DPM(c) = \{ (10^6 / Ts) \times Sum[E(I) \times Hp(I) \times To(I) \times (1 - R(o)) \times (1 - R(f)) \times (1 - R(e))] / 1.7 \times Q(f) \} + I$ ".

13. On page 58207, second column, insert before line 17, "Ts = Total shift length, hours".

14. On page 58207, second column, after line 21 and before the section heading, "VI. Impact Analysis," insert the following: "Note: The factor 1.7 to convert Q in cfm to m<sup>3</sup>/hr is determined as follows: 1 cu ft = ((2.54 cm/in)<sup>3</sup> × (12 in)<sup>3</sup>/cu ft) / ((100 cm)<sup>3</sup>/m<sup>3</sup>) = 0.028317 m<sup>3</sup>; 1 min = 1/60 hr; 1 cfm = 1.7 m<sup>3</sup>/hr; 1 gm = 10<sup>6</sup> µg; Thus Q(m<sup>3</sup>/hr) = 1.7 × Q (cu ft/min) and E(µg/hp-hr) = 10<sup>6</sup> × E(gm/hp-hr)".

## II. Corrections to Proposed Rule on Diesel Particulate Matter Exposure of Underground Coal Miners (63 FR 17492)

[Figure V-5]:

1. On page 17567, Figure V-5, section 1, "MEASURED OR ESTIMATED IN MINE DP EXPOSURE ( $\mu\text{g}/\text{m}^3$ )" should read "MEASURED OR ESTIMATED DPM CONCENTRATION ( $\mu\text{g}/\text{m}^3$ )".

2. On page 17567, Figure V-5, section 2, line 18, "AVERAGE TOTAL SHIFT PARTICULATE OUTPUT (gm)" should read "AVERAGE, TOTAL SHIFT, ENGINE EMISSION RATE (gm/hp-hr)".

3. On page 17569, first column, line 19, " $E(a) = (DPM(m) - I) \times (Q(I)/35200) / [\text{Sum}(Hp(I) \times To(I))]$ " should read " $E(a) = (DPM(m) - I) \times Ts \times Q(I) \times 1.7 / [10^6 \times \text{Sum}(Hp(I) \times To(I))]$ ".

4. On page 17569, first column, line 29, " $To(I)$  = Individual engine operating times, hours" should read " $Ts$  = Total shift length, hours".

5. On page 17569, first column, after line 30 and before line 31, insert the following before beginning of paragraph: " $To(I)$  = Individual engine operating times, hr"; " $1.7$  = The metric conversion factor that converts  $\text{cfm}$  to  $\text{m}^3/\text{hr}$ ,  $1.7$ "; " $10^6$  = The conversion factor that converts  $\text{gm}$  to  $\mu\text{g}$ ".

6. On page 17569, second column, line 19, " $DPM(a) = \{[\text{Sum}(E(I) \times Hp(I) \times To(I))] \times 35,300/Q(I) + I\} \times [Ts/8]$ " should read " $DPM(a) = [E(a) \times \text{Sum}(Hp(I) \times 10^6/1.7 \times Q(I)) + I] \times Ts/8$ ".

7. On page 17569, second column, line 22, "35,300 is a metric conversion factor" should be deleted.

8. On page 17569, second column, line 26, " $E(I)$  = Individual engine emission rates, gm/hp-hr" should read " $E(a)$  = is the quantity calculated for section 2, Column B, the average engine emission rate, gm/hp-hr".

9. On page 17569, second column, line 30, " $To(I)$  = Operating time hours" should be deleted.

10. On page 17569, second column, after line 33 and before line 34, insert the following before the beginning of paragraph: " $1.7$  = The metric conversion factor that converts  $\text{cfm}$  to  $\text{m}^3/\text{hr}$ ,  $1.7$ "; " $10^6$  = The conversion factor that converts  $\text{gm}$  to  $\mu\text{g}$ ".

11. On page 17570, first column, line 19, " $DPM(c) = \{\text{Sum}[E(I) \times Hp(I) \times To(I) \times (35300/Q(I)) \times (1-R(o)) \times (1-R(f)) \times (1-R(e))] \times [Q(I)/Q(f)]\} + I$ " should read " $DPM(c) = \{(10^6/Ts) \times \text{Sum}[E(I) \times Hp(I) \times To(I) \times (1-R(o)) \times (1-R(f)) \times (1-R(e))] / 1.7 \times Q(f)\} + I$ ".

12. On page 17570, first column, insert in line 41, " $Ts$  = Total shift length, hours".

13. On page 17570, first column, after line 47 and before the section heading,

"VI. Impact Analysis": insert the following: "Note: The factor 1.7 to convert  $Q$  in  $\text{cfm}$  to  $\text{m}^3/\text{hr}$  is determined as follows:  $1 \text{ cu ft} = ((2.54 \text{ cm/in})^3 \times (12 \text{ in})^3/\text{cu ft})/[(100 \text{ cm})^3/\text{m}^3] = 0.028317 \text{ m}^3$ ;  $1 \text{ min} = 1/60 \text{ hr}$ ;  $1 \text{ cfm} = 1.7 \text{ m}^3/\text{hr}$ ;  $1 \text{ gm} = 106 \mu\text{g}$ ; Thus  $Q(\text{m}^3/\text{hr}) = 1.7 \times Q(\text{cu ft/min})$  and  $E(\mu\text{g}/\text{hp-hr}) = 10^6 \times E(\text{gm}/\text{hp-hr})$ ".

## II. Close of Rulemaking Records

The post-hearing comment periods for both proposed rules will close concurrently on July 26, 1999.

Commenters are encouraged to submit their comments on or before that date. This will allow the public 15 months from the date of publication to comment on the underground coal proposal, and nine months to comment on the metal and nonmetal proposal.

Dated June 30, 1999.

**J. Davitt McAteer**

*Assistant Secretary for Mine Safety and Health.*

[FR Doc. 99-17326 Filed 7-6-99; 9:45 am]

BILLING CODE 4510-43-P

## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 938

[PA-124-FOR]

#### Pennsylvania Regulatory Program

**ACTION:** Proposed rule; reopening of public comment period.

**SUMMARY:** OSM is reopening the public comment period on certain parts of a proposed amendment to the Pennsylvania permanent regulatory program (hereinafter referred to as the Pennsylvania program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment was submitted on December 18, 1998, with revisions submitted on June 1, 1999. The comment period is being reopened for changes that deal with effluent limitations in 25 PA Code Chapter 87, Subchapter F and Chapter 88, Subchapter G. Specifically, these changes include the deletion of the definition of "best professional judgement" at 25 PA Code 87.202 and 25 Pa Code 88.502, and the deletion of subsections 25 PA Code 87.207 (b) and 25 PA Code 88.507 (b). Both §§ 87.207(b) and 88.507(b) are titled, "Treatment of Discharges" and require operator treatment of preexisting discharges which are not encountered during mining or implementation of the abatement plan with the effluent limits

established by best professional judgement. The amendment is intended to revise the State program to be consistent with the counterpart Federal provisions.

**DATES:** Written comments must be received by 4:00 p.m. on July 23, 1999.

**ADDRESSES:** Written comments should be mailed or hand-delivered to Mr. Robert J. Biggi, Director, Harrisburg Field Office at the first address listed below.

Copies of the Pennsylvania program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays:

Office of Surface Mining Reclamation and Enforcement, Harrisburg Field Office, Third Floor, Suite 3C, Harrisburg Transportation Center, 415 Market Street, Harrisburg, Pennsylvania 17101, Telephone: (717) 782-4036.

Pennsylvania Department of Environmental Protection, Bureau of Mining and Reclamation, Rachel Carson State Office Building, Post Office Box 8461, Harrisburg, Pennsylvania 17105-8461, Telephone: (717) 787-5103.

Each requester may receive, free of charge, one copy of the proposed amendment by contacting the OSM Harrisburg Field Office.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert J. Biggi, Director Harrisburg Field Office, Telephone: (717) 782-4036.

#### SUPPLEMENTARY INFORMATION:

#### I. Background on the Pennsylvania Program

On July 30, 1982, the Secretary of the Interior conditionally approved the Pennsylvania program. Background on the Pennsylvania program, including the Secretary's findings and the disposition of comments, can be found in the July 30, 1982, **Federal Register** (47 FR 33079). Subsequent actions concerning the Pennsylvania program amendments are identified at 30 CFR 938.15.

#### II. Discussion of the Proposed Amendment

The Pennsylvania Department of Environmental Protection (PADEP) submitted a proposed amendment to its program pursuant to remining and reclamation, postmining discharges, and water supply protection/replacement in a letter dated December 18, 1998 (Administrative Record No. PA-853.01). This proposed amendment was