

agreed upon number of hours spent in independent study. The student may still be considered in full-time attendance if the scheduled rate of attendance is below 20 hours per week if the Board finds that:

- (1) The school attended does not schedule at least 20 hours per week and going to that particular school is the student's only reasonable alternative; or
- (2) The student's medical condition prevents him or her from having scheduled attendance of at least 20 hours per week. To prove that the student's medical condition prevents him or her from scheduling 20 hours per week, the Board may request that the student provide appropriate medical evidence or a statement from the school; or

(3) The student is not attending classes, but is graduating in that month and classes ended the month before.

(d) An individual is not a full-time student if, while attending an elementary or secondary school, he or she is paid compensation by an employer who has requested or required that the individual attend the school. An individual is not a full time student while he or she is confined in a penal institution or correctional facility because he or she committed a felony after October 19, 1980.

(e) A student who reaches age 19 but has not completed the requirements for a secondary school diploma or certificate and who is a full-time elementary or secondary student, as defined in paragraph (a) of this section, will continue to be eligible for benefits until the first day of the first month following the end of the quarter or semester in which he or she is then enrolled, or if the school is not operated

on a quarter or semester system, the earlier of:

- (1) The first day of the month following completion of the course(s) in which he or she was enrolled when age 19 was reached; or
- (2) The first day of the third month following the month in which he or she reached age 19.

Dated: April 2, 1998.

By Authority of the Board.

**Beatrice Ezerski,**

*Secretary to the Board.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 101**

[Docket No. 96P-0338]

**Food Labeling: Health Claims; Soluble Fiber From Certain Foods and Coronary Heart Disease; Correction**

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

**ACTION:** Final rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of February 18, 1998 (63 FR 8103). The document authorizes the use, on food labels and in food labeling, of health claims on the association between soluble fiber from psyllium seed husk and reduced risk of coronary heart disease (CHD). The document was published with some errors. This document corrects those errors.

**EFFECTIVE DATE:** February 18, 1998.

**FOR FURTHER INFORMATION CONTACT:** Virginia L. Wilkening, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5483.

In FR Doc. 98-4074, beginning on page 8103 in the **Federal Register** of Wednesday, February 18, 1998, the following corrections are made:

- 1. On page 8104, in the first column, in the first full paragraph, in the eighth line, the **Federal Register** citation "(62 FR 3684)" should read "(62 FR 3584)".
- 2. On page 8106, in the second column, in the second full paragraph, in the tenth line, "(mg/dL)" should read "(mg/dL)".
- 3. On page 8107, in the first column, in the second full paragraph, in the 32d line, "24, and 26)" should read "24, 26, and 27)".
- 4. On page 8109, in the first column, under the section "E. Nature of the Food Eligible to Bear the Claim", in the first paragraph, in the ninth and tenth lines, "(7 g/d was)" should read "(7 g/d) was".
- 7. On page 8114, in the second column, in the first full paragraph, in the 18th line, "201(m)" should read "201(n)".
- 8. On page 8118, in the first column, in Reference number 15, in the third and forth lines, "LDL-Synthesis" should read "LDL-Cholesterol".
- 9. On pages 8120 and 8121, under Table 1.—Summary of Clinical Trials with Hypercholesterolemics: Psyllium and Coronary Heart Disease, the reference numbers used to identify the study references are incorrect. Table 1 is being republished in its entirety to read as follows:

TABLE 1.—SUMMARY OF CLINICAL TRIALS WITH HYPERCHOLESTEROLEMICS: PSYLLIUM AND CORONARY HEART DISEASE

| Study                     | Duration Treatment   | Number of Subjects  | Supplements (Psyllium, Placebo) Soluble Fiber g/d  | Diet Intake of groups: Sat fat % E; CHOL mg/d   | Magnitude of PSY Effect <sup>1</sup>                                      | Magnitude of Placebo Effect                                     |
|---------------------------|--|---|--|---|---|---|
| Anderson et al. (Ref. 12) | Base: 8 wk Step 1; Tx: 26 wk Step 1+supplement                           | PSY: 131<br>C: 28   | 10.2 g/d bulk laxative, cellulose<br>PSY: -7 g SF  | Sat fat: PSY- 8.3%; C- 7.7%<br>CHOL: PSY- 164 mg; C- 146 mg                                 | CHOL: -5 mg/dL (2.1%) <sup>1</sup><br>LDL-C: -5 mg/dL (2.9%) <sup>1</sup> | CHOL: +5 (2.6%)<br>LDL-C: +6 (3.9%)<br>HDL-C: no sig dif (grps) |
| Bell et al. (Ref. 13)     | Base: 12-wk Step 1; Tx: 8-wk Step 1+supplement                           | PSY: 40 (20 men)<br>Pla: 35 (18 men)                                | 10.2 g/d bulk laxative, cellulose<br>PSY: -7 g SF  | Sat fat: PSY- 8-10%; C- 7.7-8.6%<br>CHOL: PSY- 168 mg; C- 206 mg                            | CHOL: -9 mg/dL (4.2%)<br>LDL-C: -12 mg/dL (7.7%)                          | CHOL: 0<br>LDL-C: -0.2%<br>HDL-C: no sig dif (grps)             |
| Davidson et al. (Ref. 14) | Base: 8-wk Step 1; Tx: 24-wk Step 1 + PSY or control food (3 servings/d) | PSY 1 56 (31 men)<br>PSY 2 40 (24 men)<br>PSY 3 43 (28 men)<br>C 59 | 3.4 g, 6.8 g, 10.2 g/d; incorporated into foods: C foods: no PSY<br>PSY 1: -2.3 g SF,<br>PSY 2: -4.6 g;<br>PSY 3: -7 g | SAT fat: PSY- 7-8.6%; C- 7-8.6%<br>CHOL: PSY 1- 151 mg; PSY 2- 181; PSY 3- 169<br>C- 145 mg | CHOL: --3% (PSY 3)<br>LDL-C: --5% (PSY 3)                                 | CHOL: +1.7%;<br>LDL-C: +3%<br>HDL-C: No sig dif (grps)          |

TABLE 1.—SUMMARY OF CLINICAL TRIALS WITH HYPERCHOLESTEROLEMICS: PSYLLIUM AND CORONARY HEART DISEASE—  
Continued

| Study                     | Duration Treatment   | Number of Subjects                                   | Supplements (Psyllium, Placebo) Soluble Fiber g/d  | Diet Intake of groups: Sat fat % E; CHOL mg/d   | Magnitude of PSY Effect <sup>1</sup>   | Magnitude of Placebo Effect  |
|---------------------------|--|--|--|---|--|--|
| Everson et al. (Ref. 15)  | Regular diet; 5-d Base; 2 40-d periods; 11-d washout; crossover                | 20 men   | 15.3 g/d bulk laxative, cellulose<br>PSY: ~10 g SF   | SAT fat: PSY- 12%; C- 13.2 %<br>CHOL: PSY- 296 mg; C- 274 mg  | CHOL: -14 mg/dL (-5%)<br>LDL-C: -15 mg/dL (8%)   | CHOL: -1.9%;<br>LDL-C: -2.7%<br>HDL-C: No sig dif (grps)   |
| Keane et al. (Ref. 17)    | Base: 12 wk Step 1; Tx: 26 wk Step 1+supplement                                | PSY: 40 (18m, 24f)<br>C: 39 (7m, 32f)                | 10.2 g/d bulk laxative, cellulose<br>PSY: ~7 g SF  | SAT fat: PSY- 5%; C- 5.3%<br>CHOL: PSY- 145.2 mg; C- 151.1 mg   | CHOL: -8.7 mg/dL (3%)<br>LDL-C: -11.5 mg/dL (5.9%) <sup>1</sup>  | CHOL: +2 (1%)<br>LDL-C: 0<br>HDL-C: no sig dif (grps)  |
| Levin et al. (Ref. 18)    | Base: 8-wk Step 1; Tx: 16-wk Step 1+supplement                                 | PSY: 30 (26 men)<br>Pla: 28 (23 men)                 | 10.2 g/d bulk laxative, cellulose<br>PSY: ~7 g SF  | SAT fat: PSY- 6.7%; C- 6.3%<br>CHOL: PSY- 166 mg; C- 135 mg   | CHOL: -13 mg/dL (5.6%)<br>LDL-C: -13 mg/dL (8.6%)  | CHOL: 0; LDL-C -2.2%;<br>HDL-C: ~+6% (sig from PSY)  |
| Stoy et al. (Ref. 22)     | 4-wk Step 1; Step 1 + (8x5x5 wks); Grp 1: PSY-Pla-PSY; Grp 2: Pla-PSY-Pla      | 23 men   | Estimated 11.6 g/d PSY from cereal: ~8 g SF; Wheat cereal: ~3 g SF   | SAT fat: PSY: 5.1% (Grp 1) and 5.1% (Grp 2)<br>Wheat: 4.5% (Grp 1) and 5.0% (Grp 2)<br>CHOL: PSY 141-165 mg<br>Wheat: 164 mg (Grp 1), 117-170 (Grp 2)                                     | CHOL: -10 mg/dL (4%)<br>LDL-C: -11 mg/dL (6%)  | HDL-C: No sig dif (grps)   |
| Stoy et al. (Ref. 23)     | 4-wk Step 1; Step 1 + (8x5x5 wks); Grp 1: PSY-Pla-PSY; Grp 2: Pla-PSY-Pla      | 22 men   | Estimated 11.6 g/d PSY from cereal: ~8 g SF; Wheat cereal: ~3 g SF   | SAT fat: PSY: 4.8 (Grp 1) and 5.2% (Grp 2)<br>Wheat: 4.7% (Grp 1) and 5.6% (Grp 2)<br>CHOL: PSY 155-163 mg<br>Wheat: 133 mg (Grp 1), 169-172 (Grp 2)                                      | CHOL: -10 mg/dL (4%)<br>LDL-C: -11 mg/dL (6%)  | HDL-C: No sig dif (grps)   |
| Weingand et al. (Ref. 25) | Base: 12 wk Step 1; Tx: 8 wk Step 1+supplement, crossover                      | 23 (16m, 7f)   | 10.2 g/d bulk laxative, cellulose<br>PSY: ~7 g SF  | SAT fat: PSY- 8.7%; C- 9%<br>CHOL: PSY- 162 mg; C- 203-261 mg   | CHOL: -9 mg/dL (3.8%)<br>LDL-C: -11 mg/dL (6.2%) <sup>1</sup>  | HDL-C: sig higher in PSY group   |
| Jenkins et al. (Ref. 28)  | Base: 2 mo controlled Step 2 diets; Tx: 2-1 mo Step 2 diets+ cereal, crossover | Study 1: 32 (15m, 17f)<br><br>Study 2: 27 (12m, 15f) | Study 1: 11.4 g/d PSY in cereal (~7.8 g SF), wheat bran<br><br>Study 2: 12.4 g/d PSY in cereal (~8.4 g SF), wheat bran | Study 1: SAT fat: PSY- 4.6%; C- 4.6%<br>CHOL: PSY- 31 mg; C- 29 mg<br>MUFA: PSY- 6%; C- 6%<br><br>Study 2: SAT fat: PSY- 6%; C- 6%<br>CHOL: PSY- 22 mg; C-22 mg<br>MUFA: PSY- 12%; C- 12% | Study 1: CHOL: -27 mg/dL <sup>1</sup> (9.8%)<br>LDL-C: -24 mg/dL <sup>1</sup> (12.6%)<br>HDL-C: -6.6 mg/dL (11.3%) <sup>1</sup><br><br>Study 2: CHOL: -34 mg/dL <sup>1</sup> (12.6%)<br>LDL-C: -27.9 mg/dL <sup>1</sup> (14.9%)<br>HDL-C: -4.3 mg/dL <sup>1</sup> (8%) | Study 1: CHOL: -13.6 (5%) <sup>2</sup><br>LDL-C: -10 (5.5%)<br>HDL-C: -2 (3.3%)<br><br>Study 2: CHOL: -29.5 (10.7%) <sup>2</sup><br>LDL-C: -17 (9%) <sup>2</sup><br>HDL-C: -1.4 (2.6%) |

<sup>1</sup> Significant differences between treatment and placebo groups unless otherwise indicated.<sup>2</sup> Significant change across the diet phase.

Dated: April 3, 1998.

**William K. Hubbard,**  
Associate Commissioner for Policy  
Coordination.

[FR Doc. 98-9427 Filed 4-8-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Neomycin Sulfate Soluble Powder

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for use of neomycin sulfate soluble powder in water or milk as a drench or in drinking water for the treatment and control of colibacillosis in cattle (excluding veal calves), swine, sheep, and goats.

**EFFECTIVE DATE:** April 9, 1998.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

**SUPPLEMENTARY INFORMATION:** Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861, filed ANADA 200-235 that provides for use of neomycin sulfate soluble powder in water or milk as a drench or in drinking water for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep, and goats. Med-Pharmex, Inc.'s ANADA 200-235 is approved as a copy of Upjohn's NADA 11-315. The ANADA is approved as of March 9, 1998, and the regulations are amended in § 520.1484 (21 CFR 520.1484) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, the regulation incorrectly indicates that Phoenix Scientific, Inc., has an approved neomycin sulfate soluble powder product. At this time, the regulation is amended by removing the sponsor for Phoenix Scientific, Inc., in § 520.1484(b) and by revising paragraph (c)(3).

In accordance with the freedom of information provisions of 21 CFR part

20 and 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(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.

#### 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 520.1484 is amended by revising paragraph (b) and the last sentence of paragraph (c)(3) to read as follows:

#### § 520.1484 Neomycin sulfate soluble powder.

(b) *Sponsors.* See Nos. 000009, 000069, 046573, 050604, and 051259 in § 510.600(c) of this chapter.

(c) \* \* \*  
(3) \* \* \* Discontinue treatment prior to slaughter as follows: Cattle (not for use in veal calves), 1 day; sheep, 2 days; swine and goats, 3 days.

Dated: March 27, 1998.

**Stephen F. Sundlof,**

Director, Center for Veterinary Medicine.

[FR Doc. 98-9428 Filed 4-8-98; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF STATE

[Public Notice 2784]

### 22 CFR Part 121

#### Amendments to the International Traffic in Arms Regulations

**AGENCY:** Bureau of Political-Military Affairs, State.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the International Traffic in Arms

Regulations (ITAR) by removing from the U.S. Munitions List (USML), for transfer to the Department of Commerce's Commerce Control List (CCL), certain items when they are included in a commercial communications satellite licensed by the Department of Commerce. In all other cases, these items will continue to be controlled on the USML, subject to State Department licensing.

**EFFECTIVE DATE:** April 9, 1998.

**FOR FURTHER INFORMATION CONTACT:** William J. Lowell, Director, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State (703) 812-2564 or FAX (703) 875-6647.

**SUPPLEMENTARY INFORMATION:** On October 26, 1996, the Department published an amendment to the ITAR to remove commercial communications satellites from the USML for transfer to licensing jurisdiction by the Department of Commerce. That amendment also covered certain USML items specified in Category XV(f) when they were included in a commercial comsat launch. In all other cases, however, these items remained on the USML. Recently, the Department, in consultation with the Departments of Commerce and Defense, has decided to elaborate the earlier amendment to include satellite fuel and certain additional USML items that may be included with a commercial communications satellite licensed by the Department of Commerce.

In carrying out this decision, the Note following Category XV(f)(9), describing those USML items that may be included in a Commerce licensed commercial communications satellite, is amended.

This amendment involves a foreign affairs function of the United States and, thus, is excluded from the procedures of Executive Order 12866 (58 FR 51735) and 9 U.S.C. 533 and 554, but has been reviewed internally by the Department to ensure consistency with the purposes thereof.

In accordance with 5 U.S.C. 808, as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (the "Act"), the Department of State has found for foreign policy reasons that notice and public procedure under section 251 of the Act is impracticable and contrary to the public interest. However, interested parties are invited to submit written comments to the Department of State, Office of Defense Trade Controls, ATTN: Regulatory