

In FR Doc. 96-4914, appearing on page 8214 in the Federal Register of Monday, March 4, 1996, the following corrections are made:

1. On page 8214, under "SUPPLEMENTARY INFORMATION," in lines 14 and 29 "§ 5.98" is corrected to read "§ 5.99".

§ 5.31 [Corrected]

In § 5.31 *Petitions under part 10*, the following corrections are made:

2. On page 8215, in paragraphs (f)(1)(vi), (f)(2)(x), and (f)(8), "5.98" is corrected to read "5.99".

§ 5.98 [Redesignated]

3. § 5.98 *Issuance of notices relating to proposals and orders for debarment of an application to terminate debarment* the section number is redesignated as § 5.98.

Dated: March 14, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-6667 Filed 3-20-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 172

[Docket No. 87F-0179]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra; 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 January 30, 1996 (61 FR 3118). The document amended the food additive regulations to provide for the safe use of sucrose esterified with medium and long chain fatty acids (olestra) as a replacement for fats and oils. The document was published with some typographical errors. This document corrects those errors.

DATES: The regulation is effective January 30, 1996. Submit written comments on the labeling requirement (§ 172.867(c)) by April 1, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3092.

In FR Doc. 96-1584, appearing on page 3118 in the Federal Register of Tuesday, January 30, 1996, the following corrections are made:

1. On page 3119, in the second column, in the first footnote, in the sixth line, the last word "volum" is corrected to read "volume"; in the same column, in the second footnote, in the seventh line, "FAC" is corrected to read "FAC"; and in the eighth line, the word "meetins" is corrected to read "meetings". On the same page, in the third column, in the third full paragraph, in the eleventh line, after the period, the plus sign is removed.

2. In the following places the paragraph symbol that printed inadvertently is removed: On page 3120, in the second column, in the third paragraph, in the nineteenth line, following the word "at"; in the third column, in the first paragraph, in the fifteenth line, following the word "in"; and in the same column, in the third paragraph, in the eighteenth line, following the word "vitamins"; on page 3135, in the third column, in the third paragraph, at the beginning of the fourth line; on page 3166, in the third column, at the beginning of the twenty-first line; and on page 3169, in the third column, in the first paragraph, in the thirty-second line, following the word "to".

3. On page 3121, in the first column, in the sixth line, "vitamin" is corrected to read "vitamins".

4. On page 3124, in the first column, in the fourth full paragraph, in the third line, "250 F" is corrected to read "250 °F".

5. On page 3125, in the third column, in the second paragraph, in the twelfth line, following the word "that", the comma is removed.

6. On page 3126, in the third column, in the first full paragraph, in the eighteenth line, and on page 3127, in the first column, in the second paragraph, in the eleventh line, "CO2" is corrected to read "CO₂".

7. On page 3126, in the third column, in the first paragraph, in the twentieth line "14C-sucrose" is corrected to read "14C-sucrose".

8. On page 3129, in the first column, in the tenth line, the closing parenthesis is removed following the word "review", and reinserted following "NTP", and in the same column, in the thirteenth footnote, beginning in the first line the words "was chief" are corrected to read "was formerly chief".

9. On page 3130, in the third column, in the second paragraph, in the twenty-third line, "C14-labeled" is corrected to read "14C-labeled".

10. On page 3131, in the first column, in the first paragraph, in the thirteenth

line, "C14-labeled" is corrected to read "14C-labeled".

11. On page 3132, in the second column, in fifteenth line, "Vitamin K" is corrected to read "vitamin K", and in the same column, in both the twentieth and twenty-first footnotes, and in the third column, in the twenty-second footnote, "vol." is corrected to read "vol. 2".

12. On page 3135, in the first column, in the twenty-fourth footnote, in the fourth line, "baseline" is corrected to read "baseline", and in the second column, in the first paragraph, in the tenth line, "1,25-(OH)D" is corrected to read "1,25-(OH)₂D".

13. On page 3136, in the second column, in the second full paragraph, in the seventh line, the word "vitamin" is removed, and on the same page, in the third column, in the sixth line, "K1" is corrected to read "K₁".

14. On page 3137, in the first column, in the second full paragraph, in the fifth line, "3H-labeled" is corrected to read "3H-labeled".

15. On page 3138, in the second column, in the first paragraph, in the third line, and in the third column, in the third line, "B12" is corrected to read "B₁₂".

16. On page 3144, in the third column, in the second paragraph, in the eleventh line, the word "that" is removed.

17. On page 3147, in the third column, in the first paragraph, in the thirteenth line, insert a comma after the word "cancer", and in the same column, in the forty-first footnote, the sentences "Dr. Alvan Feinstein is Chief of the Clinical Epidemiology Unit and a Sterling Professor of Medicine and Epidemiology at Yale University School of Medicine. Dr. Feinstein has consulted for the petitioner and presented at its request." are added after the footnote number.

18. On page 3148, in the first column, in the first full paragraph, in the third line; in the second paragraph, in the second and twenty-fifth lines; in the second column, in the sixteenth line; and in the first paragraph, in the fourth line, the word "carotenoid" is corrected to read "carotenoids".

19. On page 3151, in the third column, in the fifty-fifth footnote, in the second line, the name "Schneemna" is corrected to read "Schneeman".

20. On page 3152, in the second column, in the first full paragraph, in the sixth line, "IV.B.1.a." is corrected to read "IV.B.1.".

21. On page 3153, in the second column, in the fourteenth line, the word "was" is removed, and in the same column, in the sixtieth footnote, the

name "Joann" is corrected to read "Joanne".

22. On page 3156, in the third column, in the sixth line, "to safe" is corrected to read "to be safe", and in the same column, in the first full paragraph, in the fourth line, the word "stated" is removed.

23. On page 3158, in the first column, following the footnote, "⁷² Transcript, vol. 1, p. 152." the misplaced sentence "Accordingly, the petitioner concluded * * * by intestinal microflora." is removed and reinserted in the same column as a new last sentence of the second paragraph, following the words "metabolize olestra.⁷²" On the same page, in the third column, in the second paragraph, in the eighth line, "section VI.3." is corrected to read "section VI.B.3."

24. On page 3163, in the second column, in the third paragraph, in the third and twenty-second lines, "(Ref. 105)" is corrected to read "(Ref. 104)".

25. On page 3167, in Table 10, in the second column, in the last line, "K₁/g olestra" is corrected to read "K₁/g olestra".

26. On page 3171, in the first column, in Ref. 102, in the fifth line, "pp. 783-799." is corrected to read "pp. 783-799,"; and in the third column, in § 172.867, in paragraph (b)(6), in the first line, "C12" and "C14" are corrected to read "C₁₂" and "C₁₄", in the third line "C20" is corrected to read "C₂₀", and in the fourth line, "C16" and "C18" are corrected to read "C₁₆" and "C₁₈".

§ 172.867 Corrected

27. On page 3172, in the third column, in § 172.867 *Olestra*, in paragraph (d), in the fifth line, the word "lacetate" is corrected to read "acetate", and in the seventh line, "K¹" is corrected to read "K₁". In the same column, in paragraph (e)(1), in the fourth line of the warning statement "and other other nutrients" is corrected to read "and other nutrients", and in paragraph (e)(2)(iv), in the first line, the word "kearned" is corrected to read "kerned".

Dated: March 13, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-6741 Filed 3-20-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 573

[Docket No. 94F-0282]

Food Additives Permitted in Feed and Drinking Water of Animals; Poly(2-vinylpyridine-co-styrene)

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations (animal use) to provide for the safe use of the food additive poly(2-vinylpyridine-co-styrene) as a coating agent in the preparation of rumen-stable, abomasum-dispersible nutrient products for dairy cattle. This action is in response to a food additive petition filed by Rhone-Poulenc Animal Nutrition.

DATES: Effective March 21, 1996; written objections and request for hearing by April 22, 1996.

ADDRESSES: Submit written objections and requests for hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sharon A. Benz, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1729.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of August 11, 1994 (59 FR 41326), FDA announced that a food additive petition (animal use) (FAP 2231) had been filed by Rhone-Poulenc Animal Nutrition, 42, Avenue Aristide Briand, B.P. 100, 92164 Antony Cedex, France. The petition proposed to amend the food additive regulations in § 573.870 (21 CFR 573.870) to provide for the safe use of poly(2-vinylpyridine-co-styrene) as a coating agent in the preparation of rumen-stable, abomasum-dispersible nutrient products for dairy cattle and dairy replacement heifers. The additive is currently listed in § 573.870 as safe for use as a nutrient protectant in feed for beef cattle.

The notice of filing provided for a 75-day comment period. One comment has been received in response to the notice and is on file in the Dockets Management Branch (address above). The comment raised several questions concerning the fate and effects of poly(2-vinylpyridine-co-styrene) and its components released into the environment. Questions concerned the degradation rate when applied to the land as manure fertilizer, and degradation endpoint products. The

comment also questioned whether the polymer or its monomers (styrene and 2-vinylpyridine) resulted in bioaccumulation, movement into groundwater, and/or pollutant uptake by animals and plants.

FDA has reviewed the environmental assessment and supporting studies for use of poly(2-vinylpyridine-co-styrene) in dairy cattle feed. The amount expected to enter the soil environment from a typical consumption of 10 to 25 grams of rumen protected amino acid per head per day via manure from treated animals is 1.06 parts per million. The polymer is expected to be strongly adsorbed by soil and to have a low mobility. Therefore, it is not expected to move in significant quantities to surface or groundwater due to agricultural runoff. The environmental assessment states that no more than trace quantities are likely to enter the aquatic environment and no subsequent bioconcentration is expected. The environmental assessment demonstrates that 1.31 pounds of each of the monomers are expected to enter the environment each year resulting in soil concentrations of 0.21 parts per trillion (ppt) and air point source concentrations of 60 ppt. Therefore, the two monomers are not expected to have a significant effect on the environment. The information in the environmental assessment is sufficient to address the questions raised in the comment and adequate to conclude that significant environmental impacts are not expected to occur.

FDA has evaluated the data in the petition and other relevant material and concluded that use of poly(2-vinylpyridine-co-styrene) for dairy cattle (including replacement dairy heifers) in addition to the use for beef cattle as a nutrient protectant in feed is safe. Therefore, § 573.870 is amended as set forth below.

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person listed above. As provided in 21 CFR 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no