

available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a lubricant and release agent as defined in § 170.3(o)(18) of this chapter and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter; chewing gum as defined in § 170.3(n)(6) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; herbs, seeds, spices, seasoning blends, extracts, and flavorings as defined in § 170.3(n)(26) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

g. By adding new § 184.1443, to read as follows:

§ 184.1443 Magnesium sulfate.

(a) Magnesium sulfate ($MgSO_4 \cdot 7H_2O$, Cas Reg. No. 10034-99-8) occurs naturally as the mineral epsomite. It is prepared by neutralization of magnesium oxide, hydroxide, or carbonate with sulfuric acid and evaporating the solution to crystallization.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 183, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter;

and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: nonalcoholic beverages and beverage bases as defined in § 170.3(n)(3) of this chapter and condiments and relishes as defined in § 170.3(n)(8) of this chapter.

The agency is unaware of any prior sanction for the use of these ingredients in foods under conditions different from those identified in this document. Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The action proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), and the failure of any person to come forward with proof of an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on it later. Should any person submit proof of the existence of a prior sanction, the agency hereby proposes to recognize such use by issuing an appropriate final rule under Part 181 (21 CFR Part 181) or affirming it as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

Interested persons may, on or before March 22, 1983 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 29, 1982.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-1683 Filed 1-20-83; 8-45 am]
BILLING CODE 4160-01-M

21 CFR Parts 182 and 184

(Docket No. 81N-0381)

Manganese Salts; Proposed Affirmation and Removal of GRAS Status as Direct Human Food Ingredients

Correction

In FR Doc. 82-34257, beginning on page 56513 in the issue of Friday,

December 17, 1982, make the following correction.

On page 56513, third column, twelfth line of the second complete paragraph, the last word in the line reading "the" should read "and".

BILLING CODE 1505-01-M

21 CFR Part 201

(Docket No. 82N-0158)

Labeling of Salicylate-Containing Drug Products; Correction

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the advance notice of proposed rulemaking advising that the agency is considering proposing to require certain over-the-counter (OTC) and prescription salicylate-containing drug products for human use to bear a warning against the use of the products for the treatment of flu or chicken pox in children or adolescents under 16 years of age, because salicylates may be associated with the development of Reye Syndrome in this age group. The advance notice of proposed rulemaking was published in the Federal Register of December 28, 1982.

FOR FURTHER INFORMATION CONTACT: Paul O. Fehnel, Jr., National Center for Drugs and Biologics (HFN-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

SUPPLEMENTARY INFORMATION: In FR Doc. 82-35065 at page 57888 in the Federal Register of Tuesday, December 28, 1982, the following corrections are made:

1. On page 57892 in the third column, in the first sentence of the first full paragraph, "antecent" is changed to "antecedent."

2. On page 57896 in the third column in the next to last sentence in the second full paragraph, "(Refs. 113 and 114)" is added after "undertaken"; and in the fourth sentence in the third paragraph, "(Ref. 105)" is added after "announced".

3. On page 57898 in the fourth line in the first column, "(Refs. 113 and 114)" is added after "products".

4. On page 57901 in the third column, two references are added after reference 112. The references are:

113. HHS press release on Reye Syndrome dated September 20, 1982.

114. Statement by Edward N. Brandt, Jr., M.D., before the Subcommittee on National Resources, Agriculture Research and Environment, Committee on Science and Technology, U.S. House of Representatives, September 29, 1982.

Dated: January 14, 1983.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-1521 Filed 1-20-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 201

[Docket No. 82N-0158]

Labeling for Salicylate-Containing Drug Products

Correction

In FR Doc. 82-35065 beginning on page 57886 in the issue of Tuesday, December 28, 1982 make the following corrections.

1. On page 57886, column one summary, line five "salicylate-containing" should read salicylate-containing.
2. On page 57886, column two, paragraph two, lines thirteen, fourteen, and fifteen, delete "but its incidence may be 30 to 60 per 100,000 persons under 18 years of age (Ref. 2)."
3. On page 57886, column three, paragraph three, line two "by" should read "be."
4. On page 57887, column one, paragraph one, line thirteen, "amont" should read "among."
5. On page 57887, column one, paragraph two, line four, "on" should read "of."
6. On page 57887, column one, paragraph two, line eleven "the" should appear between "about" and "accuracy."
7. On page 57887, column one, paragraph three, line six, "too" should read "took."
8. On page 57887, column one, paragraph designated as "B.", line nine, delete the word "as."
9. On page 57887, column three, paragraph designated as "3.", line one, "wrtitten" should read "written."
10. On page 57889, column two, paragraph one, line twenty-four, "user" should read "use" and "by" should appear between "use" and "cases."
11. On page 57890, column one, paragraph designated as "3.", line seven, "statistial" should read "statistical."
12. On page 57892, column one, paragraph three, line two from the bottom, "has" should read "had."
13. On page 57892, column three, line twenty-three, delete the word "a."

14. On page 57892, column three, paragraph one, line twenty, "Rs" should read "RS."

15. On page 57893, column one, paragraph designated as "8.", line twelve, "salicylate" should read "salicylates."

16. On page 57893, column two, paragraph two, line nine, "diffeential" should read "differential."

17. On page 57893, column three, line eight, the words "acetaminophen product longer than they would remember administering a" should appear between "an" and "salicylate."

18. On page 57894, column two, paragraph designated as "12.", line 16, there should be a space between "I" and "RS."

19. On page 57894, column three, paragraph two, line eight, "case" should read "cases."

20. On page 57895, column one, paragraph two, line five, "results" should read "result."

21. On page 57895, column one, paragraph two, line fourteen "salicylism" should read "salicylate."

22. On page 57895, column one, paragraph designated as "14.", line twelve, "phosphorylatin" should read "phosphorylation."

23. On page 57895, column three, paragraph one, line eighteen "rhevmatoid" should read "rheumatoid."

24. On page 57896, column two, line twenty-four, "delegate" should read "delegated."

25. On page 57896, column two, paragraph two, line seven "100,0900" should read "100,000."

26. On page 57896, column two, paragraph two, line eleven "result" should read "results."

27. On page 57896, column two, paragraph two, line fifteen "take" should read "taken."

28. On page 57897, column one, paragraph one, line twelve, "necessarily" should read "necessarily."

29. On page 57897, column two, paragraph designated as "5.", line five "Reyes" should read "Reye."

30. On page 57897, column three, paragraph designated as "B.", line twelve "Reyes" should read "Reye".

31. On page 57898, column one, lines thirteen and twenty-two, "Reyes" should read "Reye."

32. On page 57898, column one, line twenty-eight, "working" should read "wording."

33. On page 57898, column three, line six, "us" should read "use".

34. On page 57901, column two, paragraph designated as "108.", line two "dted" should read "dated."

BILLING CODE 1505-01-M

DEPARTMENT OF TREASURY

Internal Revenue Service

26 CFR Part 1

[LR-236-81]

Credit for Increasing Research Activity

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed amendments to the income tax regulations to provide rules for the new credit for increasing research activities. Changes to the applicable tax law were made by the Economic Recovery Tax Act of 1981.

DATE: Written comments and requests for a public hearing must be delivered or mailed by March 25, 1983. These amendments are proposed to be effective for purposes of determining if and to what extent amounts paid or incurred after June 30, 1981, and before January 1, 1986, qualify for the research credit. The amendments to § 1.174-2 are proposed to be effective for taxable years beginning after 1953, but the Internal Revenue Service will not require changes in the treatment of expenses for purposes of section 174 on returns filed before the publication of a treasury decision on this subject merely because of these amendments.

ADDRESS: Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224, Attention: CC:LR:T (LR-236-81).

FOR FURTHER INFORMATION CONTACT: John R. Harman of the Legislation & Regulations Division, Office of Chief Counsel, 202-566-3238, not a toll-free call.

SUPPLEMENTARY INFORMATION:

Background

The credit for increasing research activities is provided by section 44F of the Internal Revenue Code of 1954, as added by section 221 of the Economic Recovery Tax Act of 1981 (Pub. L. 97-34; 95 Stat. 241). These proposed amendments, if adopted, will be issued under the authority contained in section 44F (f) (1)-(4) and section 7805 of the Internal Revenue Code of 1954 (95 Stat.