8, 1994, * * * will apply to all food products labeled on or after May 8, 1994, rather than to all food products initially introduced into interstate commerce on or after that date." The Nutrition Labeling and Education Act of 1990 (the 1990 amendments), the amendments to the act that provided the explicit authority for these regulations, does not permit the agency to establish a later date of application. In fact, the May 8, 1994, date already represents agency exercise of the maximum flexibility provided to it by Congress in the 1990 amendments. Without an explicit FDA finding that undue economic hardships would result, the date of application of the regulations would have been May 8, 1993 (58 FR 2070). Therefore, nonexempt products labeled on or after May 8, 1994, and not bearing required nutrition labeling will be out of compliance with the act.

Recently, two issues have been brought to the agency's attention:

1. In the **Federal Register** of August 18, 1993 (58 FR 44033 at 44035), the agency stated "The term 'labeled' means the date that the label is affixed to the product or product container." It has been reported that there are some in the food industry who are interpreting this sentence as permitting the manufacture of food product containers bearing labels in conformance with existing regulations and then warehousing the finished containers to be filled with food products after the May 8, 1994, date of application. Under this scenario, a manufacturer could stockpile huge quantities of empty containers and avoid changing labels for weeks or even months.

This view is a complete misreading of the August 18, 1993, document. FDA included the term "or product container" in the sentence in question to ensure that the sentence covered situations in which food is labeled by affixing a label to the container in which it is enclosed, as well as those in which the label is affixed to the food. The sentence was not included to provide a means of avoiding the May 8, 1994, applicability date.

The agency expects that all products coming off a manufacturer's production line on May 8, 1994, after 12:01 a.m. will bear the required nutrition labeling, whether the food is directly labeled or put into containers. FDA inspectors will be instructed to examine the product as it leaves the production line. Any manufacturer who is filling improperly labeled containers will not be in compliance with the act.

2. Recently, the agency has received a number of requests from a variety of manufacturers asking for extensions of time to comply with, or even for exemptions from, the nutrition labeling regulations. Many of these requests cite potentially significant monetary losses because large quantities of label inventory must be destroyed. Others state that they will be unable to comply with the regulations because they have been unable to obtain necessary nutrient values, or because printing facilities have become saturated.

As stated previously in the document, FDA has no authority to grant exemptions from nutrition labeling beyond those in the act and provided for in the agency's regulations. Also, FDA cannot further delay the date of applicability beyond May 8, 1994, regardless of the economic hardships on the specific manufacturer. The agency further points out that the labeling in question is required nutrition information that both Congress and FDA consider important to the public health. The food industry has known since November 8, 1990, that such labeling would be required and, thus, has had over 3 years to plan for this transition. Additionally, even if FDA were able to grant extensions, the agency would question the fairness to the large segment of the food industry that has already invested the time and expense of converting its food labels in order to meet the May 8, 1994, date of applicability.

FDA recognizes that there may be a very small number of firms that will be unable to come into compliance despite all good faith efforts to do so. While FDA is not unwilling to consider the extraordinary circumstances presented by these few firms, the agency advises generally that a nonexempt product failing to bear nutrition labeling or bearing nutrition information inconsistent with the regulations of January 6, 1993, as modified on August 18, 1993, will be out of compliance if labeled on or after May 8, 1994.

FDA has received reports of firms that have a significant supply of containers or labels that will not be used up by the May 8, 1994, applicability date. The agency points out that such firms need not dispose of such containers or labels but can use them if they can be brought into compliance through the use of stickers that comply with the new regulations placed on the noncomplying container or label. In no case, however, can FDA grant an exemption in these circumstances.

Thus, FDA will not be issuing letters of exemption or extensions to the mandatory nutrition labeling regulations beyond those confirming exemptions or extensions formally recognized under the act or provided for under 21 CFR 101.9(g)(9) because compliance is technologically infeasible or impracticable.

The agency reaffirms that a product labeled after May 8, 1994, that does not comply with section 403(q) and 403(r)(2) of the the act is misbranded. Also, the agency states that no further extension to the date of applicability is possible under the act.

Dated: March 25, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94-7632 Filed 3-28-94; 1:49 pm]

BILLING CODE 4160-01-F

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21 CFR Parts 20 and 101

[Docket No. 85N-061D]

RIN 0905-AB67

Food Labeling; General Requirements for Health Claims for Dietary Supplements; 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 4, 1994 (59 FR 395). The document amended the food labeling regulations to provide for health claims for dietary supplements. The document was published with an editorial error. This document corrects that error.

EFFECTIVE DATE: July 1, 1994.

FOR FURTHER INFORMATION CONTACT: James R. Taylor, Jr., Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

In FR Doc. 93-31815, appearing on page 395 in the **Federal Register** of Tuesday, January 4, 1994, the following corrections are made:

On page 395, in the first column, in the "**EFFECTIVE DATE**" caption, the "July 5, 1994" is corrected to read "July 1, 1994".

§ 101.14 [Corrected]

2. On page 425, in the third column, in § 101.14 *Health claims: general requirements* in paragraph (e)(6), in line 1, the phrase "Except for dietary supplements," is corrected to read "Except for dietary supplements or where provided for in other regulations in part 101, subpart E,".

Dated: March 25, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–7626 Filed 3–30–94; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 101

[Docket No. 91N–384D]

RIN 0905–AD96

Food Labeling; Requirements for Nutrient Content Claims for Dietary Supplements of Vitamins, Minerals, Herbs, and Other Similar Nutritional Substances; 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 4, 1994 (59 FR 378). The document amended the food labeling regulations to provide for nutrient content claims for dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances. The document was published with some errors. This document corrects those errors.

EFFECTIVE DATE: July 1, 1995.

FOR FURTHER INFORMATION CONTACT: Camille E. Brewer, 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. 93–31814, appearing on page 378 in the **Federal Register** of Tuesday, January 4, 1994, the following corrections are made:

1. On page 378, in the third column, in line 4 of the title of the document, the word "Nutritionnal" is corrected to read "Nutritional".

2. On page 382, in the second column, in the second full paragraph, in line 14, the parenthetical phrase "(except as limited by section 411(b)(2)(B) of the act)" is added after the words "for sugar".

3. On page 385, in the third column, in line 10, the word "provides" is corrected to read "provide".

4. On page 386, in the third column, in the second full paragraph, in line 9, the phrase "comment 25" is corrected to read "comments 25 and 26".

§ 101.13 [Corrected]

5. On page 394, in the first column, in § 101.13 **NUTRIENT CONTENT CLAIMS—GENERAL PRINCIPLES** in paragraph (j)(1)(i)(B), in the last line, " and" is added after the word "multivitamin)".

§ 101.54 [Corrected]

6. On page 394, in the first column, in § 101.54 *Nutrient content claims for "good source," "high," and "more"* in paragraph (b)(1), in line 3, the word "and" is corrected to read "or".

Dated: March 25, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–7628 Filed 3–30–94; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 130 and 155

Food Standards; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations for canned vegetable products by correcting certain inadvertent errors; and its regulations for temporary marketing permits by correcting a mailing address used for filing such applications. This action is being taken to improve the accuracy of the regulations. These actions are editorial in nature and do not change the substance of any of the regulations in question.

EFFECTIVE DATE: March 31, 1994.

FOR FURTHER INFORMATION CONTACT: Nannie H. Rainey, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION: FDA has discovered that certain inadvertent errors have been incorporated into the agency's codified regulations pertaining to temporary marketing permits and to canned tomatoes and certain other canned vegetables. Because these errors are nonsubstantive, FDA finds that there is good cause to correct them without engaging in rulemaking. Given the nature of the errors, notice and public procedure are unnecessary under the Administrative Procedure Act (5 U.S.C. 553). This final rule addresses the following errors in the regulations:

1. In § 130.17(c) (21 CFR 130.17(c)), the agency is correcting the office name and address for the place where temporary marketing permit applications should be filed. As a result of the 1992 reorganization of the Center for Food Safety and Applied Nutrition, the correct name and address is the Food Standards Branch, Office of Food Labeling, Center for Food Safety and Applied Nutrition (HFS–158), 200 C St. SW., Washington, DC 20204. Accordingly, FDA is correcting § 130.17(c).

2. In § 155.190(a)(3)(iv) (21 CFR 155.190(a)(3)(iv)), the reference to "§§ 155.191 and 155.192," should be changed to "§ 155.191." Section 155.192 was removed in the **Federal Register** of January 28, 1983 (48 FR 3946 at 3956) and the effective date confirmed in the **Federal Register** of March 31, 1993 (58 FR 16771).

3. In 21 CFR 155.200(g), the reference to "§ 101.122" is incorrect. The correct reference is "§ 101.22".

List of Subjects

21 CFR Part 130

Food additives, Food grades and standards.

21 CFR Part 155

Food grades and standards, Vegetables.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 130 and 155 are amended as follows:

PART 130—FOOD STANDARDS: GENERAL

1. The authority citation for 21 CFR part 130 continues to read as follows:

Authority: Secs. 201, 306, 401, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 341, 343, 371).

2. Section 130.17 *Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity* is amended in the introductory text of paragraph (c) by removing the words "Deputy Director, Division of Food Chemistry and Technology, Center for Food Safety and Applied Nutrition (HFF–410), Food and Drug Administration" and adding in its place "Chief, Food Standards Branch, Office of Food Labeling, Center for Food Safety and Applied Nutrition (HFS–158)".

PART 155—CANNED VEGETABLES

3. The authority citation for 21 CFR part 155 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U S.C. 321, 341, 343, 348, 371, 379e).

§ 155.190 [Amended]

4. Section 155.190 *Canned tomatoes* is amended in paragraph (a)(3)(iv) by removing the phrase "§§ 151.191 and 155.192" and adding in its place "§ 155.191".

§ 155.200 [Amended]

5. Section 155.200 *Certain other canned vegetables* is amended in the first sentence of paragraph (g), by removing "§ 101.122" and adding in its place "§ 101.22".

Dated: March 25, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–7627 Filed 3–30–94; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 821

[Docket No. 91N–0296]

Medical Devices; Illustrative and Designated Lists for Device Tracking; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule and request for comments; correction

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of August 16, 1993 (58 FR 43451), which amended the medical device tracking regulations to add the temporo-mandibular joint prostheses to the illustrative list of devices and the penile inflatable implant to the list of devices designated for tracking. The document was published with a typographical error. This document corrects that error.

EFFECTIVE DATE: August 29, 1993.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4765.

In FR Doc. 93–19470, appearing on page 43451, in the **Federal Register** of Monday, August 16, 1993, the following correction is made:

§ 821.20 [Amended]

On page 43455, in the 3d column, in amendatory instruction 2b. for § 821.20, in line 5, "878.5725" is corrected to read "880.5725".

Dated: March 25, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–7629 Filed 3–30–94; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Exempt Chemical Preparations

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim rule and request for comments.

SUMMARY: This interim rule amends the list of exempt chemical preparations set Forth in section 1308.24(i) of Title 21 of the Code of Federal Regulations. This action is in response to DEA's periodic review of the exempt chemical preparation list and of new applications for exemptions filed with DEA. Preparations included in the list are exempted from the application of specific provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and from certain Drug Enforcement Administration Regulations.

DATES: Effective Date: March 31, 1994. Comments must be submitted on or before May 2, 1994.

ADDRESSES: Comments and objections should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; Attention: Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., (Chief, Drug & Chemical Evaluation Section), 202–307–7183.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act as amended by the Dangerous Drug Diversion Control Act of 1984 authorizes the Attorney General in accordance with 21 U.S.C. 811(g)(3)(B) to exempt from specific provisions of the Act, a compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal and which is packaged in such form or concentration, or with adulterants or denaturants, so that, as packaged, it does not present any significant potential for abuse. This authority ultimately has been delegated to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

The Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, has received applications pursuant to § 1308.23 of title 21 of the Code of Federal Regulations requesting approval of exempt status provided for in 21 CFR 1308.24. The Deputy Assistant Administrator hereby finds that each of the following preparations and mixtures is intended for laboratory, industrial, educational, or special research purposes, is not intended for general administration to man or animal, and either (a) contains no narcotic controlled substances and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse, (b) contains either a narcotic or non-narcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration that the preparation or mixture does not present any potential for abuse, or (c) the formulation of such preparation or mixture incorporates methods of denaturing or other means so that the controlled substance cannot in practice be removed, and therefore the preparation or mixture does not present any significant potential for abuse. The Deputy Assistant Administrator further finds that exemption of the following chemical preparations and mixtures is consistent with the public health and safety as well as the needs of the researchers, chemical analysts, and suppliers of these products.

The listing of products in 21 CFR 1308.24(i) exempts persons who handle them from certain sections of the Controlled Substances Act of 1970 and its regulations. The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that these matters will have no significant impact upon small businesses or other entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. Accordingly, the Deputy Assistant Administrator certifies this action will have no impact on the ability of small businesses to compete and he therefore determines that no regulatory flexibility analysis is required.

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this matter does not have sufficient federalism implications to require the preparation of a Federalism Assessment.

The Office of Management and Budget (OMB) has determined that listings of exempt chemical preparations are exempt from centralized review under Executive Order 12866.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 202(d) of