21 CFR Part 101

[Docket Nos. 96P–0500 and 91N–384H]

RIN 0910–AA19

Food Labeling: Nutrient Content Claims, Definition of Term: Healthy

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial stay.

SUMMARY: The Food and Drug Administration (FDA) is announcing a partial stay of certain provisions of the nutrient content claim regulations pertaining to the use of the term ''healthy.'' This action is in response to a citizen's petition from ConAgra, Inc. (the petitioner), to amend the definition of this term.

DATES: Effective April 1, 1997 21 CFR 101.65(d)(2)(ii)(C) and (d)(4)(ii)(B) are stayed until January 1, 2000. Written comments by May 1, 1997.

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: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5483.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 10, 1994 (59 FR 24232 at 24249), FDA published a final rule to establish a definition of the term ''healthy'' under section 403(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)). Under § 101.65(d)(2)(ii) (21 CFR 101.65(d)(2)(ii)), for a food to qualify to use the term ''healthy,'' or a derivative of that term, on its label or in its labeling, the food must contain no more than 480 milligrams (mg) of sodium per reference amount customarily consumed (RACC) before January 1, 1998 (§ 101.65(d)(2)(ii)(A) and (d)(2)(ii)(B)), and no more than 360 mg of sodium per RACC after January 1, 1998 (§ 101.65(d)(2)(ii)(C)). Under § 101.65(d)(4)(ii), main dish and meal products, to qualify to bear this term, must contain no more than 600 mg of sodium per RACC before January 1, 1998 (§ 101.65(d)(4)(ii)(A)), and no more than 480 mg of sodium per RACC after January 1, 1998 (§ 101.65(d)(4)(ii)(B)).

On December 13, 1996, FDA received from the petitioner, ConAgra, Inc., 888 17th Street, suite 300, NW., Washington, DC 20006, a petition requesting that § 101.65(d) be amended to ''eliminate the sliding scale sodium requirement for foods labeled 'healthy' by eliminating the entire second tier levels of 360 mg sodium for individual foods and 480 mg sodium for meals and main dishes.'' Alternatively, the petitioner requested that the effective date of January 1, 1998, in § 101.65(d)(2) through (d)(4), be delayed until such time as food technology ''catches up'' with FDA's goals to reduce the sodium content of foods, and there is a better understanding of the relationship between sodium and hypertension.

The petitioner cited as grounds for its requests: (1) A lack of scientific basis supporting the Daily Reference Value for sodium and the allowable levels of sodium in § 101.65(d); (2) a lack of consumer acceptance of products containing low sodium levels; (3) a lack of acceptable sodium substitutes and the difficulties in manufacturing whole lines of food products at low sodium levels; and (4) FDA's failure to provide notice and comment on the ''second tier'' sodium levels in the healthy definition, to follow directives of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), and to consider all the science, stating that recent studies indicate a concern if too little sodium is consumed (Docket 96P–0500, CP1, p. 3). While FDA finds little merit in the first and last of these grounds, the middle two raise questions that merit further consideration.

Relative to the efforts of industry to lower the sodium level in foods, the petitioner stated that the technology does not yet exist to manufacture certain low fat products at the ''healthy'' definition levels of sodium that will be required in 1998 and still provide foods that will be acceptable to consumers. The petitioner submitted the results of a consumer survey that examined consumer acceptance of several products with different sodium levels. While the survey found reductions in consumer acceptance at levels of 480 mg sodium compared to higher sodium levels, much greater, i.e., statistically significant, drops occurred at levels of 360 mg sodium per serving. As stated by the petitioner:

> If the sodium is so low in a product as to render the product tasteless or even bad tasting, consumers will not eat the product or will reach for the table salt. This is counter-productive to the intent of the 1990 amendments and will not result in the goal Congress envisioned; i.e., to improve the eating habits of the American public, but instead could result in even more salt intake—not less.

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The petitioner also delineated several technological concerns with lowering sodium levels in foods related to the functional role of salt, such as impacts on the microbial stability of perishable products, changes in product texture and in water binding capacities, and effects on flavor characteristics of other ingredients and on total electrolyte levels that play a critical role in product safety.

Important issues have been raised in this petition regarding the technological feasibility of further reductions in the sodium levels in certain foods that currently meet FDA's definition of ''healthy'' and regarding the palatability of such foods after the sodium has been reduced. The agency recognizes that the food industry has made a significant effort over the past few years to lower both the fat and sodium levels in food products while maintaining taste and texture attributes that are acceptable to consumers. The agency continues to believe, however, that the scientific evidence indicates further reductions in fat and sodium intakes will result in meaningful public health gains.

FDA has defined the term ''healthy'' to serve as a means to help consumers identify food products that will help them meet dietary guidelines for a healthy diet. Consumers appreciate the significance of this term, and thus many make purchasing decisions based on its presence on a food label. Because of this fact, manufacturers have an incentive to produce foods that qualify to bear this term. If the petitioner is correct that the technology does not yet exist that will permit manufactures to produce certain types of low fat foods that will contain the lower levels of sodium required by January 1, 1998, and still be acceptable to consumers, then the possibility exists that ''healthy'' will disappear from the market for such foods. If this situation comes to pass, FDA will have squandered a significant opportunity. Therefore, the agency finds that, before the new sodium levels for ''healthy'' go into effect, it needs to explore whether it has created an unattainable standard for many types of foods.

Under the provisions of § 10.35(a) and (d)(1), the Commissioner of Food and Drugs (the Commissioner) may at any time stay or extend the effective date of a pending action if the Commissioner determines that it is in the public interest to do so. As discussed previously in this document, the petition has raised significant issues that have public health implications. FDA also recognizes, as mentioned in the petition, that manufacturers must begin very soon to revise the formulations and the labeling, if they have not already done so, for those products that do not currently comply with the requirements that must be met after January 1, 1998, for a product to bear the claim ''healthy.'' Time is

needed for the agency to complete its review of the issues raised by the petition. Additionally, FDA believes that it should seek comment on these issues from other interested persons. Given these factors, the agency is persuaded that it is in the public interest to stay the provisions for the lower standards for sodium in the definition of ''healthy'' in § 101.65 while the agency endeavors to resolve the issues raised by the petition.

Therefore, the agency is staying the provisions for further reducing the sodium level in foods labeled as ''healthy'' until January 1, 2000, to allow time for FDA to reevaluate the standard, including the data contained in the petition and any additional data that the agency may receive, to conduct any necessary notice-and-comment rulemaking, and for industry to respond to the rule or to any change in the rule that may result from the agency's reevaluation.

To assist the agency in its reevaluation, FDA intends to issue an advance notice of proposed rulemaking (ANPR) in the near future to ask for comments on the petition as well as for additional data regarding the technological feasibility of reducing the sodium content of individual foods to 360 mg per RACC and of meals and main dishes to 480 mg sodium per RACC. The agency will also be seeking comments on other approaches to reduce the amount of sodium in foods labeled ''healthy.'' It is important that consumers seeking to eat a health-promoting diet have food choices that enable them to further reduce the amount of sodium in their diet. Interested persons need not wait for the publication of the ANPR but should feel free to review the petition and to submit to the agency any information or views they have on consumer acceptance of foods with low sodium levels and on the lack of acceptable sodium substitutes and the difficulties in manufacturing lines of food products with low sodium levels.

Accordingly, FDA is announcing a stay of the provisions in § 101.65(d)(2)(ii)(C) and (d)(4)(ii)(B) until January 1, 2000. Interested persons may also submit comments regarding the appropriateness of the basis of this stay. In doing so, however, FDA encourages manufacturers who can meet the lower sodium levels for particular foods and still produce an acceptable product to do so even as the agency reevaluates the issues discussed previously in this document.

Interested persons may, on or before May 1, 1997 submit to the Dockets Management Branch (address above) written comments regarding this document. 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.

This document is issued under sections 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

For the reasons set forth in the preamble, 21 CFR 101.65(d)(2)(ii)(C) and (d)(4)(ii)(B) are stayed until January 1, 2000.

Dated: March 26, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–8127 Filed 3–31–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 556 and 558

Animal Drugs, Feeds, and Related Products; Tilmicosin Phosphate Type A Medicated Article; 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 December 27, 1996 (61 FR 68147). The document amended the animal drug regulations to reflect approval of Elanco Animal Health's new animal drug application (NADA) 141–064 for use of a Type A medicated article containing tilmicosin phosphate in manufacturing a Type B or Type C medicated feed indicated for the control of swine respiratory disease associated with certain bacterial organisms. The document was published with some errors. This document corrects those errors.

EFFECTIVE DATE: December 27, 1996.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

In FR Doc. 96–32881, appearing on p. 68147, in the **Federal Register** of Friday, December 27, 1996, the following corrections are made:

§ 556.735 [Corrected]

1. On page 68148, in the second column, in line 2, ''7.2'' is corrected to read ''7.5''.

§ 558.618 [Corrected]

2. On page 68148, in the second column, in paragraph (d)(1), ''181.8'' and ''363.6'' are corrected to read ''181'' and ''363'', respectively.

Dated: February 7, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–8116 Filed 3–31–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1309 and 1310

[DEA No. 132C]

RIN 1117–AA33

Consolidation, Elimination, and Clarification of Various Regulations; Correction

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to the final regulations (DEA 132) which were published on Monday, March 24, 1997 (62 FR 13938). The regulations related to the consolidation, elimination, and clarification of DEA's regulations as part of the President's National Performance Review, Regulatory Reinvention Initiative.

EFFECTIVE DATE: April 1, 1997.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: The final regulations that are the subject of these corrections revise Title 21, Code of Federal Regulations (CFR), Chapter II in accordance with the President's Regulatory Reinvention Initiative. As published, the final regulations contain errors that could cause confusion in the regulated industry. Specifically, the final regulations did not take into account the amendment of certain definitions and the amendment of 21 CFR 1310.09 that were included in an Interim Rule published by DEA on February 10, 1997 (62 FR 5914), which