

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91 N-0102]

RIN 0905-AD08

Food Labeling: Health Claims; Zinc and Immune Function In the Elderly

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize the use on the label or labeling of foods of health claims relating to an association between ingestion of zinc and immune function in the elderly. This rule is issued in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and is developed in accordance with the final rule on general requirements for health claims, issued elsewhere in this issue of the **Federal Register**. The agency has concluded that, based on the totality of the scientific evidence, there is not-significant scientific agreement among qualified experts that increased intake of zinc will enhance immune function in the elderly. Therefore, FDA has concluded that claims on foods relating to zinc and immune function in the elderly are not justified.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60652), FDA proposed not to authorize health claims relating to zinc and immune function in the elderly. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537, November 27, 1991). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or

(r)(5)(D) of the act (21 U.S.C. 343(r)(3) or (r)(5)(D)).

Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain good health through appropriate dietary patterns and to protect consumers from unfounded health claims. Section 3(b)(1)(A) of the 1990 amendments specifically requires the agency to determine whether claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The relationship of zinc and immune function in the elderly is one of the claims required to be evaluated. In the proposed rule (56 FR 60652), FDA reviewed the publicly available relevant data pertaining to zinc and immune function in the elderly and evaluated whether health claims relating zinc and immune function would be justified under the standard proposed in the companion document entitled "Food Labeling: General Requirements for Health Claims for Food" (56 FR 60537).

FDA published a notice in the **Federal Register** of March 28, 1991 (56 FR 12932), requesting scientific data and information on the 10 specific topic areas identified in the 1990 amendments, including zinc and immune function in the elderly. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on zinc and immune function, and were included in the proposed rule (56 FR 60652).

In the proposed rule (56 FR 60652), FDA requested written comments on its tentative determination not to authorize a health claim for zinc and immune function in the elderly. In addition, FDA held public hearings on January 30 and 31, 1992, on all aspects of the proposed rules published to effect the 1990 amendments (57 FR 239, January 3, 1992). The agency received approximately 20 comments in response to its proposal to deny health claims regarding zinc and immune function in the elderly. Several comments were received that were more appropriately addressed in other documents, and these comments were forwarded to the appropriate docket for response.

The relevant publicly available data evaluated by FDA in its proposed rule (56 FR 60652) included seven human studies (Refs. 29 through 35) in which elderly subjects were supplemented with zinc to determine its influence on immune system function. In the proposed rule (56 FR 60652 at 60661), the results of four of the earlier published studies (Refs. 29 through 32)

suggested a zinc-associated enhancement of several measures of immune function. However, FDA noted that the reliability of three of these studies was limited due to inclusion of very few individuals, and the rested subjects were not representatives of the general elderly population. Moreover, FDA further noted that the results of these initial reports have not been substantiated by more recent, larger studies of more rigorous experimental design (Refs. 34 and 35).

FDA tentatively concluded that the later, larger studies showed no improvement of immunocompetence from zinc supplementation in the elderly. The agency also pointed out that zinc supplementation at levels in excess of 100 milligrams per day (mg/day) can result in suppression of immune system function (Ref. 48). For these reasons, FDA tentatively determined that claims on foods, including dietary supplements, relating to zinc and immune function in the elderly are not justified.

The Dietary Supplement Act of 1992 established a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. The law says that FDA can grant health claims for foods, including dietary supplements, using the significant scientific agreement standard specified in section 403(r)(3)(B)(i) of the act. However, it may not act on such claims under section 403(r)(5)(D) of the act until it establishes a standard to implement that section of the act, which the new law says may not occur until December 1993. Section 3(b)(1)(A)(x) of the 1990 amendments directs the agency to evaluate the zinc and immune function claim based on the standard that FDA is establishing for determining the reliability of health claims under section 403(r)(5)(D) of the act. In the November 27, 1991 proposal, on general requirements for health claims, FDA proposed to adopt the standard that the 1990 amendments provide for conventional foods, which is set forth in section 403(r)(3)(B)(i) of the act, as the standard for dietary supplements. Given this fact, and the fact that zinc is found in numerous conventional foods as well as in dietary supplements, FDA broadened its inquiry to a determination as to whether it should grant a health claim on zinc and immune function in the elderly on any foods.

Because the Dietary Supplement Act provides that FDA may grant claims under section 403(r)(3)(B)(i) of the act, and given the breadth of FDA's November 1991 proposal, on zinc, FDA has decided to move forward to

determine whether it can authorize a claim under section 403(r)(3)(B)(i) for zinc and immune function.

However this rule does not apply to dietary supplements. While a manufacturer of a dietary supplement can make a claim on zinc and immune function in the elderly without rendering its product misbranded under section 403(r)(1)(B) of the act, the manufacturer should assure itself that the making of the claim will not misbrand the product under section 403(a) of the act.

II. Comments to the Proposal and the Agency's Responses

A. General

1. Nine comments representing State attorney generals, State agencies associations of public health officials, and professional associations of people employed in nutrition-related fields agreed with FDA's assessment of the evidence on zinc and immune function, including FDA's proposed decision not to authorize a claim on this nutrient-disease relationship. Several comments stated opposition to allowing health claims in general.

The agency acknowledges those comments supporting its tentative position not to authorize a health claim on zinc and immune function in the elderly. In response to those comments that oppose all health claims, however, the agency points out that the 1990 amendments provide sufficient safeguards to ensure that health claims are scientifically valid and will provide consumers with information that will promote good health.

B. Comments on the Available Data

2. One comment from a consumer-oriented nutrition magazine noted that the small number of participants in some of the studies cited in the proposed rule (56 FR 60652) makes their inclusion questionable. This comment also noted that results from studies using supplemental zinc levels no higher than the Recommended Dietary Allowance would likely be of little value.

FDA concurs with this comment. In its proposed rule, FDA noted that small (5 to 8 subjects), uncontrolled studies (Refs. 30 through 32) were included among those that it found in its review of the publicly available scientific literature. However, in the proposed rule, the agency stated that the significance of these reports to the agency's decision was limited because of the small number of subjects and the lack of substantiation of their findings by larger studies.

Of the three studies in which supplemental zinc was provided at the Recommended Dietary Allowance level (12 to 15 mg/day), two studies (Refs. 34 and 35) also included substantially higher supplemental zinc levels (100 mg/day). FDA stated that the third study (Ref. 31), which used a 15 mg/day zinc supplement, was of low reliability because of the limited number of subjects, absence of control subjects with which to compare those supplemented with zinc, and lack of blinding as to treatment received.

3. One comment submitted a list of recently published scientific studies, not cited in the proposed rule, suggesting that they bear directly or indirectly on the issue.

FDA reviewed the submitted studies and determined that not one of the articles is relevant to the topic of zinc and immune function in the elderly. Of the six references listed, five were of studies of zinc metabolism or nutrition, but did not involve immune function. One reference listed did concern zinc and immune function, but was available only as an abstract. FDA did not consider abstracts in its evaluation as experimental design and data are presented too briefly for adequate evaluation.

C. Life Science Research Office Report

4. Among the authoritative documents considered in the proposed rule was a preliminary report (Ref. 26) from a 1991 review of the literature on the relationship between zinc and immune functions in the elderly conducted by the Life Sciences Research Office (LSRO) of the Federation of American Societies of Experimental Biology (FASEB). The final version of the LSRO report ("Evaluation of Publicly Available Scientific Evidence Regarding Certain Nutrient-Disease Relationships: 2. Zinc and Immune Function in the Elderly", W. R. Beisel) was released by LSRO in December 1991, and filed in the docket as a comment on the proposed rule. The final version was not changed from the preliminary version cited and discussed in the proposed rule. It fully supports FDA's conclusions on the lack of a relationship between zinc and immune function in the elderly.

D. Canada

5. In two comments, the Canadian Government (Bureau of Consumer Affairs, and Health and Welfare Canada) noted that, under the Canadian Food and Drug Act, Section 3, the advertising and sale of foods represented as a treatment, preventative, or cure for specified diseases and health problems

is prohibited in Canada. Although immune function is not included among the list of specified disorders, health claims respecting zinc and immune function on food labels would likely result in the foods being classified as drugs in Canada by virtue of the definition for "drug" in the Canadian law.

These comments are essentially identical to a comment submitted by the Canadian Government in response to FDA's notice requesting scientific data or information on this topic, which published in the **Federal Register** of March 28, 1991 (56 FR 12932). In its proposed rule (56 FR 60652), FDA did not propose to authorize health claims for zinc and immune function on food labels. Thus, no change in the proposed rule is appropriate in response to this comment.

III. Conclusion

FDA reviewed the scientific data in conformity with the requirements of the 1990 amendments, as well as comments received regarding the proposed rule that published in the **Federal Register** of November 27, 1991 (56 FR 60652), and concluded that there is not a sufficient basis to support the use of health claims relating to the topic of zinc and immune function in the elderly.

The agency's examination of publicly available evidence found that, although it is well accepted that adequate dietary zinc is essential for normal immune function, a specific protective role of zinc supplementation of the elderly population has not been demonstrated. Although some small early clinical studies suggested such a relationship, these results were not substantiated in subsequent research using better study designs and larger samples. Therefore, there is no evidence that immune function in healthy persons can be enhanced by zinc supplementation. Zinc is considered to be relatively nontoxic, particularly if taken orally. However, adverse effects, which include impaired immune function, are known to occur with zinc intake in excess of Recommended Dietary Allowances. Thus, FDA has concluded that the publicly available data on the role of zinc in immune system function do not provide a sufficient scientific basis from which to conclude that immune function in the general elderly U.S. population can be improved by zinc supplementation. Moreover, based on the totality of this evidence, there is not significant scientific agreement among qualified experts that a health claim for zinc and immune function in the elderly is supported by the evidence.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this section 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.

V. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the \$100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354, FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that, although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD

20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Beisel, W. R., "Future Role of Micronutrients on Immune Functions," *Annals of the New York Academy of Sciences*, 587:267-274, 1990.

2. Chandra, R. K., "Nutrition, Immunity, and Infection: Present Knowledge and Future Direction," *Lancet*, March 26:688-691, 1983.

3. Chandra, R. K., "Micronutrients and Immune Functions: An Overview," *Annals of the New York Academy of Sciences*, 567:9-16, 1990.

4. Thompson, J. S., J. Robbins, and J. K. Cooper, "Nutrition and Immune Function in the Geriatric Population," *Clinics in Geriatric Medicine*, 3:309-317, 1987.

5. Cunningham-Rundles, S., R. S. Bookman, A. Lin, P. V. Giardina, M. W. Hilgartner, D. Caldwell-Brown, and D. M. Carter, "Physiological and Pharmacological Effects of Zinc on Immune Response," *Annals of the New York Academy of Sciences*, 587:113-122, 1990.

6. Fraker, P. J., M. E. Gershwin, R. A. Good, and A. S. Prasad, "Interrelationships Between Zinc and Immune Function," *Federation Proceeding*, 45:1474-1479, 1986.

7. Keen, C. L. and M. E. Gershwin, "Zinc Deficiency and Immune Function," *Annual Review of Nutrition*, 10:415-431, 1990.

8. Sherman, A. R. and N. A. Hallquist, "Immunity," in Present Knowledge in Nutrition, 6th ed., edited by M. L. Brown. International Life Sciences Institute-Nutrition Foundation, Washington, DC, pp. 463-476, 1990.

9. Fosmire, G. J., "Zinc Toxicity," *American Journal of Clinical Nutrition*, 51:225-227, 1990.

10. Chandra, R. K., "Nutrition and Immunity: Lessons From the Past and New Insights into the Future," *American Journal of Clinical Nutrition*, 53:1087-1101, 1991.

11. Fletcher, M. P., "Immune Function in the Elderly," *Frontiers of Radiation Therapy and Oncology*, 20:38-44, 1986.

12. Kay, M. M. B., "Immunobiology of Aging," in "Nutrition, Immunity and Illness in the Elderly," edited by R. K. Chandra. Pergamon Press, New York, pp. 97-119, 1985.

13. Chandra, R. K., P. Joshi, B. Au, G. Woodford, and S. Chandra, "Nutrition and Immunocompetence of the Elderly: Effect of Short-term Nutritional Supplementation on Cell-mediated Immunity and Lymphocyte Subset," *Nutrition Research*, 2:223-232, 1982.

14. Greger, J. L., "Potential for Trace Mineral Deficiencies and Toxicities in the Elderly," in "Mineral Homeostasis in the Elderly," edited by C. W. Bales, Alan R. Liss, Inc., pp. 171-199, 1989.

15. Pennington, J. A. T., B. E. Young, D. B. Wilson, R. D. Johnson, and J. E. Vanderveen, "Mineral Content of Foods and Total Diets: The Selected Minerals in Food Survey, 1982-1984," *Journal of American Diet Association*, 86:876-891, 1986.

16. Sahyoun, H. R., C. L. Otradovec, S. C. Hartz R. A. Jacob, H. Peters, R. M. Russell, and R. B. McGandy, "Dietary Intakes and Biochemical Indicators of Nutritional Status in an Elderly, Institutionalized Population,"

American Journal of Clinical Nutrition, 47:524-533, 1988.

17. Bunker, V. W. and B. E. Clayton, "Research Review: Studies in the Nutrition of Elderly People with Particular Reference to Essential Trace Elements," *Age and Ageing*, 18:422-429, 1989.

18. Moser-Veillon, P. B., "Zinc: Consumption Patterns and Dietary Recommendations," *Journal of the American Diet Association*, 90:1089-1093, 1990.

19. Sandstead, H. H., L. K. Henriksen, J. L. Greger, A. S. Prasad, and R. A. Good, "Zinc Nutriture in the Elderly in Relation to Taste Acuity, Immune Response, and Wound Healing," *American Journal of Clinical Nutrition*, 36:1046-1059, 1982.

20. Prasad, A. S., "Trace Element Status of the Elderly," in "Nutrition, Immunity and Illness in the Elderly," edited by R. K. Chandra, Pergamon Press, New York, pp. 62-76, 1985.

21. Morley, J. E., A. D. Mooradian, A. J. Silver, D. Heber, and R. B. Alfin-Slater, "Nutrition in the Elderly," *Annals of Internal Medicine*, 109:890-904, 1988.

22. U.S. Department of Health and Human Services (DHHS), Public Health Service (PHS), "The Surgeon General's Report on Nutrition and Health," DHHS (PHS) Publication No. 017-001-00465-1, U.S. Government Printing Office, Washington, DC, 1988.

23. U.S. Department of Agriculture (USDA) and DHHS, "Nutrition and Your Health: Dietary Guidelines for Americans," Home and Garden Bulletin, No. 232, 3d ed., U.S. Government Printing Office, Washington, DC 1990.

24. National Academy of Sciences, National Research Council, Committee on Diet and Health, "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.

25. National Academy of Sciences, National Research Council, Food and Nutrition Board, "Recommended Dietary Allowances," 10th ed., National Academy Press, Washington, DC, 1989.

26. LSRO, "Zinc and Immune Function in the Elderly," FASEB (under contract number FDA 223-88-2124), Bethesda, MD, 1991.

27. Canada National Health and Welfare, "Nutrition Recommendations: The Report of the Scientific Review Committee, 1990," Canadian Government Publishing Centre, Ottawa, Canada, 1990.

28. DHHS and USDA, "Nutrition Monitoring in the United States: A Progress Report from the Joint Nutrition Monitoring Evaluation Committee," DHHS Publication No. (PHS) 86-1255, U.S. Government Printing Office, Washington, DC, 1986.

29. Duchateau, J., G. Delespesse, R. Vrijens, and H. Collet, "Beneficial Effects of Oral Zinc Supplementation on the Immune Response of Old People," *American Journal of Medicine*, 70:1001-1004, 1981.

30. Wagner, P. A., J. A. Jernigan, L. P. Bailey, C. Nickens, and G. Brazzi, "Zinc Nutriture and Cell-mediated Immunity in the Aged," *International Journal for Vitamin and Nutritional Research*, 53:94-101, 1983.

31. Soltesz, K. S., J. H. Williford, L. P. Renker, and L. A. Meserve, "Zinc Nutriture

and Cell Mediated Immunity in Institutionalized Elderly," *Journal of Nutrition for the Elderly*, 8:3-17, 1988.

32. Cossack, Z. T., "T-lymphocyte Dysfunction in the Elderly Associated with Zinc Deficiency and Subnormal Nucleoside Phosphorylase Activity: Effect of Zinc Supplementation," *European Journal of Cancer and Clinical Oncology*, 25:973-976, 1989.

33. Bracker, M. D., W. Hollingsworth, P. D. Saltman, L. G. Strause, M. R. Klauber, and N. J. Lugo, "Failure of Dietary Zinc Supplementation to Improve the Antibody Response to Influenza Vaccine," *Nutrition Research*, 8:99-104, 1988.

34. Bogden, J. D., et al., "Zinc and Immunocompetence in Elderly People: Effects of Zinc Supplementation for 3 Months," *American Journal of Clinical Nutrition*, 48:655-663, 1988.

35. Bogden, J. D., et al., "Effects of One Year of Supplementation with Zinc and Other Micronutrients on Cellular Immunity in the Elderly," *Journal of American College Nutrition*, 9:214-225, 1990.

36. Turnlund, J. R., N. Durkin, F. Costa, and S. Margen, "Stable Isotope Studies of Zinc Absorption and Retention in Young and Elderly Men," *Journal of Nutrition*, 116:1239-1247, 1986.

37. DHHS, Interagency Committee on "Nutrition Monitoring, Nutrition Monitoring in the United States: The Directory of Federal Nutrition Monitoring Activities," DHHS Publication No. (PHS) 89-1255-1, U.S. Government Printing Office, Washington, DC, 1989.

38. Pennington, J. A. T. and B. E. Young, "Total Diet Study Nutritional Elements," 1982-1989, *Journal of the American Diet Association*, 91:179-183, 1991.

39. Swanson, C. A., R. Mansourian, H. Dirren, and C. H. Rapin, "Zinc Status of Healthy Elderly Adults: Response to Supplementation," *American Journal of Clinical Nutrition*, 48:343-349, 1988.

40. Schoeller, D. A., "How Accurate is Self-Reported Dietary Energy Intake?", *Nutrition Reviews*, 48:373-9, 1990.

41. National Academy of Sciences, National Research Council, Food and

Nutrition Board, Coordinating Committee on Evaluation of Food Consumption Surveys, Subcommittee on Criteria for Dietary Evaluation, "Nutrient Adequacy: Assessment Using Food Consumption Surveys," National Academy Press, Washington, DC, 1986.

42. Moss A. J., A. S. Levy, I. Kim, and Y. K. Park, "Use of Vitamin and Mineral Supplements in the United States; Current Users, Types of Products, and Nutrients, Advance Data from Vital and Health Statistics," No. 174, DHHS Publication No. (PHS) 89-1250, NCHS, Hyattsville, MD, 1989.

43. Hartz, S. C., et al., "Nutrient Supplement Use by Healthy Elderly," *Journal of the American College of Nutrition*, 7:119-128, 1988.

44. LSRO, "Assessment of the Zinc Nutritional Status of the U.S. Population Based on Data Collected in the Second National Health and Nutrition Examination Survey, 1976 to 1960," editors: S. M. Pilch and F. R. Senti, FASEB, Bethesda, MD, 1984.

45. DHHS and USDA, "Nutrition Monitoring in the United States: An Update Report on Nutrition Monitoring," DHHS Pub. No. (PHS) 89-1255, U.S. Government Printing Office, Washington, DC, 1989.

46. Prasad, A. S., "Discovery of Human Zinc Deficiency and Studies in an Experimental Human Model," *American Journal of Clinical Nutrition*, 53:403-412, 1991.

47. Yetley, E. and C. Johnson, "Nutritional Applications of the Health and Nutrition Examination Surveys (NHANES)," *Annual Review of Nutrition*, 7:441-63, 1987.

48. Chandra, R. K., "Excessive Intake of Zinc Impairs Immune Responses," *Journal of the American Association*, 252:1443-1446, 1984.

49. Duchateau, J., G. Delespesse, and P. Verecke, "Influence of Oral Zinc Supplementation on the Lymphocyte Response to Mitogens of Normal Subjects," *American Journal of Clinical Nutrition*, 34:88-93, 1981.

50. Fox, M. R. S., "Zinc Excess," in *Zinc in Human Biology*, edited by Mills C. F., Springer-Verlag, London, pp. 365-370, 1989.

51. Goodwin, J. S., W. C. Hunt, P. L. Hooper, and P. J. Carry, "Relationship Between Zinc Intake, Physical Activity, and Blood Levels of High-density Lipoprotein Cholesterol in a Healthy Elderly Population," *Metabolism*, 34:519-523, 1985.

52. Hooper, P. L., L. Visconti, P. J. Garry, and G. E. Johnson, "Zinc Lowers High-Density Lipoprotein-cholesterol Levels," *Journal of the American Medical Association*, 244:1960-1961, 1980.

List of Subjects in 21 CFR Part 101

Food labeling. Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 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).

2. Section 101.71 is amended by adding new paragraph (e) to read as follows:

§101.71 Health claims: claims not authorized.

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(e) Zinc and immune function in the elderly.

Dated: October 23, 1992.

David A. Kessler,
Commissioner of Food and Drugs.

Louis W. Sullivan,
Secretary of Health and Human Services
[FR Doc. 92-31516 Filed 12-28-92; 8:45 am]

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