



NOV - 5 1996

Mr. Richard J. Litner
Nutrinfo
40 Spring Street
P.O. Box 1097
Watertown, Massachusetts 02272-1097

Dear Mr. Litner:

This is in response to your letter of October 7, 1996 to the Food and Drug Administration (FDA) on behalf of your client J.B. Harris, Inc. Your letter responds to letters from FDA dated December 29, 1995 and March 5, 1996, in which FDA stated that J.B. Harris, Inc. was making drug claims for its product Sambucol. The claims being made for Sambucol are:

Sambucol™ is a safe and effective virus control.
Sambucol™ stops viruses in the throat before they spread.

As stated in both of our previous letters, these statements evidence that this product is intended for other than food use within the meaning of 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the act), in that it is intended for use as an antiviral agent. A claim that a product is for other than food use within the meaning of section 201(g) of the act makes that product subject to regulation under the drug provisions of the act. As stated in our previous letters, if your client intends to make such claims, you should immediately contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855. Since there is no information in your October 7, 1996 submission that would lead us to change our position in this matter, we do not believe that a meeting at this time would be helpful.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Chicago District Office, Office of Compliance, HFR-MW140

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200



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OFFICE OF SPECIAL
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October 7, 1996

Robert J. Moore, Ph.D.
Senior Regulatory Specialist
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutritionals
Food and Drug Administration
200 C Street
HFS-455
Washington, DC 20204

Re: J.B. Harris, Inc.
Dietary Supplement: Sambucol
FDA Chicago District Inspection: September 20, 1996

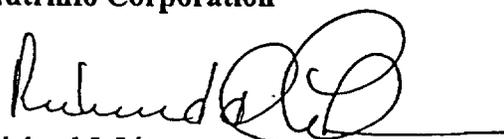
Dear Mr. Moore,

Enclosed please find the response of J.B. Harris, Inc. to a request made by Investigator Geraldine Phipps of the Chicago District Office for samples of labeling used by our client in connection with its product, Sambucol.

This response concerns by the Agency's view that statements of nutritional support made for Sambucol constitute drug claims. As noted in the enclosed materials, we request a conference with appropriate agency officials to review this matter prior to any regulatory action being taken against our client. We will contact Ms. Phipps to arrange these conferences.

Cordially,

Nutrinfo Corporation


Richard J. Litner

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- A virus itself is not a disease and the presence of viruses in the throat does not constitute an infection.
- Inactivating a virus does not make a product a drug. The fact that some drugs are classified as antiviral agents does not mean that all antiviral agents must be classified as drugs.
- There are many physiological activities which can be accomplished by both drug and nondrug products. The existence of drugs which claim to affect body structure or function does not preclude dietary supplements from claiming the same effects.
- A product which claims only to support healthy body structure or function serves to reduce the risk of disease. A claim to promote good health should not be considered a drug claim, even though the claim implies a reduced risk of disease.

These issues are important to dietary supplement regulations in general. Prior to any regulatory action being taken against our client we respectfully request to meet personally with Mr. Miracco, Dr. Robert Moore, Senior Regulatory Scientist, Office of Special Nutritionals and other appropriate Agency officials to resolve these, and other, substantive issues.

In February, 1996, Dr. Elizabeth Yetley, Director, Office of Special Nutritionals, in referring to notices of statements of nutritional support filed with the Agency, stated at an industry conference

"...we may write back to a manufacturer that has submitted or a submitter of one of these notifications and indicate problems that they may have. At some point we could take regulatory action, but at this time we are new at the game, and you are new at the game, and we are trying to get a feel for this..."

Dr. Yetley's statements suggest that regulatory action by the Agency against dietary supplement manufacturers for statements of nutritional support would not be taken until the regulatory policy for dietary supplements called for by the DSHEA was established.

Section 15 of the Dietary Supplement Health and Education Act of 1994 (DSHEA) states that Congress finds-

- (A) Legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and
- (B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.

Although Congress created the Commission on Dietary Supplement Labels (Section 12 of the DSHEA), with a mandate to provide recommendations for the regulation of label claims, to date this commission has not proffered any guidance with respect to statements of nutritional support. At its September 20, 1996 meeting the Commission noted many key, unresolved issues with respect to statements of nutritional support and stated that its report might not be completed until April 30, 1997.

We suggest that until the Commission on Dietary Supplement Labels has issued its report and/or the Agency has issued proposed regulations providing guidelines to dietary supplement manufacturers that it is premature to take regulatory action against J.B. Harris, Inc. and Sambucol™.

Enclosed please find additional labeling for Sambucol™ that was not available during your inspection.

We look forward to your early response.

Cordially,

Nutrinfo Corporation

Richard J. Litner
Compliance Department

DR. THOMSEN J. HANSEN
Director of Science

CURRICULUM VITAE

EXPERIENCE

Nutrinfo Corporation Watertown, MA
Director of Science
Nutrinfo is a consulting group which serves the food, drug, and dietary supplement industries. The Legal, Science, and Graphic Departments develop, review, and document labeling and claims for products in compliance with Food and Drug Administration and Federal Trade Commission regulations.

VICAM LP Watertown, MA
Director of Chemistry
VICAM develops and manufactures immunochemical tests for toxins and bacteria in foods. VICAM developed Aflatest, a monoclonal antibody affinity column test for aflatoxin, as the standard method for aflatoxin analysis.

Drexel University Philadelphia, PA
Assistant Professor, Department of Nutrition and Food Sciences
Primary research interests in the role of nutrition and chronic disease with an emphasis on food safety and analysis, including effect of diet on carcinogen metabolism. Also research in biomedical materials (with Drexel University Biomedical Engineering and Science Institute). Funding from food and medical industries and USDA.
Awards: University Research Scholar

National Cancer Institute Bethesda, MD
National Institutes of Health
Analytical Chemistry Section
Laboratory of Carcinogen Metabolism
Postdoctoral Research Chemist
Research on chemistry of nitrite and related compounds with emphasis on study of molecular energetics and reaction mechanisms by magnetic resonance.
Awards: NIH Staff Fellowship

EDUCATION

Massachusetts Institute of Technology Cambridge, MA
1980 Ph.D. Food Science and Technology
Department of Nutrition and Food Science (currently: Toxicology: Department of Chemistry)
Thesis Title: Analysis and Identification of Nitrosation Products of Foods
Minor: Analytical Chemistry
Awards: Institute of Food Technologists Fellowship

1974 Bachelor of Science in Chemistry

ASSOCIATIONS

American Chemical Society

Institute of Food Technologists
Awards: Division Chair, Institute of Food Technologists, Division of Toxicology and Safety Evaluation

BIBLIOGRAPHY

REVIEWED PUBLICATIONS

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- Chromatographic separation of conformers of substituted asymmetric nitrosamines. Iwaoka, W.T., T.J. Hansen, S.T. Hsieh and M.C. Archer. *J. Chromatogr.* 103, 349-354, 1975
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- Identification of nitrohexane in corn treated with nitrous acid. Hansen, T.J., M.C. Archer and S.R. Tannenbaum. *J. Agric. Food Chem.* 27, 1072-1075, 1979
- Characterization of pyrolysis conditions and interference by other compounds in the chemiluminescence detection of nitrosamines. Hansen, T.J., M.C. Archer and S.R. Tannenbaum. *Analyt. Chem.* 51, 1526-1528, 1979
- Identification of a nonenylnitrolic acid in corn treated with nitrous acid. Hansen, T.J., S.R. Tannenbaum and M.C. Archer. *J. Agric. Food Chem.* 29, 1008-1011, 1981
- N-Nitrosothialdine synthesis, X-ray crystallography and N-N bond rotational barrier. Hansen, T.J., R.M. Angeles, L.K. Keefer, C.S. Day and W. Gaffield. *Tetrahedron* 31, 4143-4149, 1981
- Stereochemistry of thialdine. Day, C.S., T.J. Hansen and L.K. Keefer. *J. Heterocyclic Chem.* 19, 1301-1304, 1982
- Reducing nitrosamine contamination in cutting fluids. Loepky, R.N., T.J. Hansen and L.K. Keefer. *Food Chem. Toxicol.* 21, 607-613, 1983
- Mutagenicity tests on purified 3-nitropropionic acid. Hansen, T.J. *Food Chem. Toxicol.* 22, 399-401, 1984
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- Methotrexate- anticollagen conjugate inhibits in vitro lens cell outgrowth. Hansen, T.J., R. Tyndall and D.B. Soll. *Invest. Ophthalmol. Vis. Sci.* 28, 1206-1209, 1987
- Volatiles in skin of low dose irradiated fresh chicken. Hansen, T.J., G.C. Chen and J.J. Shieh. *J. Food Sci.* 52, 1180- 1182, 1987
- Carcinogenesis in rats by cyclic nitrosamines containing sulfur. Lijinsky, W., R.M. Kovatch, L.K. Keefer, J.E. Saavedra, T.J. Hansen, A.J. Miller and W. Fiddler. *Food Chem. Toxicol.* 26, 3- 7, 1988
- Effects of low dose irradiation and post- irradiation cooking and storage on the thiamine content of fresh pork. Jenkins, R.K., D.W. Thayer and T.J. Hansen. *J. Food Sci.* 54, 1461- 1465, 1989
- Affinity column cleanup and direct fluorescence measurement of aflatoxin M1 in milk. Hansen, T.J. *J. Food Prot.* 53, 75- 77, 1990

Immunoaffinity column coupled with solution fluorometry or liquid chromatography postcolumn derivatization for determination of aflatoxins in corn, peanuts, and peanut butter: a collaborative study. Trucksess, M.W., M.E. Stack, S. Nesheim, S.W. Page, R.H. Albert, T.J. Hansen and K.F. Donahue. JAOAC 74, 81-88, 1991

Immunochemical methods for mycotoxin detection in food products. Hansen, T.J. Trends in Food Sci. Tech. 1, 83- 88, 1991

Quantitative analysis of mycotoxins. Hansen, T.J. Cereal Foods World 38, 346- 348, 1993

RECENT ABSTRACTS

Immunoaffinity isolation of fumonisin B1 and application to analysis in corn. Hansen, T.J., P.L. Skipper and N.A. Zabe. AOAC International Meeting 106, 368, 1992

Automated mycotoxin sample preparation and analysis: aflatoxins and fumonisins in corn. Jordan, L., T.J. Hansen and N.A. Zabe. AOAC International Meeting 107, 1993

A New Test for Listeria on Surfaces. Mitchell, B.A., J.A. Milbury, A.M. Brookins, Y.W. Ho, T.J. Hansen and B.J. Jackson. Annual Mtg. Inst. Food Technol. 54-1, 1994

Affinity column cleanup and direct fluorescence measurement of aflatoxin in spices. AOAC International Meeting 108, 1994

PATENTS

Mitotic inhibitor and method for preventing posterior lens capsule opacification after extracapsular extraction. Soll, D.B., T.J. Hansen and I. Kamel. U.S. patent 4,918,165. April 17, 1990

Assay method for detecting Listeria. Green, C.L., F. Fiedler, T.J. Hansen, G.N. Wogan, S.R. Tannenbaum, and T.L. Benjamin. U.S. patent 5,139,933. August 18, 1992

TECHNICAL SUMMARY

"Viruses in the Throat" is not a Disease



Thomsen J. Hansen, PhD

Director of Science

Nutrinfo Corp.

October 4, 1996

Sambucol™, a dietary supplement distributed by J. B. Harris, Inc., claims to help maintain the health of consumers who are exposed to airborne viruses. A typical claim is that Sambucol "stops viruses in the throat". Recent communications with the FDA have demonstrated their position that claims regarding virus control automatically constitute drug claims. Drug claims for a product which is not an approved drug may provoke regulatory action. Sambucol is a dietary supplement, and so cannot make drug claims.

We do not agree with the position that the virus claims made for Sambucol are drug claims. Rather, they are statements of nutritional support, which are allowed for dietary supplements. A virus by itself is not a disease, and inactivating a virus does not make a product a drug. Sambucol should be able to make claims which describe its properties in a manner which is helpful in maintaining the good health of its consumers. It does not purport to stop viruses generally or to restore immunity. If FDA persists in considering Sambucol as a drug, based on claims to stop viruses, then they may be faced with the need to regulate other products as drugs. These other products include a wide variety of safe and useful products which are not now considered to be drugs.

VIRUSES AND HEALTHY RESPONSE TO VIRUSES

Viruses are organic entities which consist of genetic material surrounded by a protective coat. By itself a virus is lifeless, but it can enter and replicate within a host cell. Replication occurs when the viral nucleic acid is copied by enzymes in the host cell. In some cases, the virus resides and replicates in the host cell with no obvious cell damage. In other cases, the virus destroys the host cell, allowing the replicated virus to enter other cells. Viruses are the agents responsible for a number of acute and chronic diseases. For acute viral diseases, such as influenza, the best treatment is to manage symptoms until the body's immune system can eliminate the infectious virus.

Viruses which may cause infections in the upper respiratory tract (including the throat) are constantly challenging the body's defenses. The best approach to prevent influenza and similar diseases is to reduce exposure to the causative virus, but this would entail avoiding all human contact. Fortunately, the healthy body has several mechanisms for defense against viruses. Otherwise, we would contract a cold or the flu every time we were exposed. Secretions in the throat prevent the virus from reaching the cell. The cell

wall itself forms a barrier to entry of the virus into the cell. The immune system generates antibodies which bind to viruses, leading to their elimination from the body. Nutritional support for these normal healthy body processes helps decrease the risk that exposure to viruses would lead to disease. In other words, the mere presence of viruses in the throat does not constitute an infection. It is a normal condition which the healthy body can tolerate without any adverse effects.

BOTH DRUGS AND NONDRUGS PROMOTE GOOD HEALTH

Vaccines are an effective way to prevent viral infections. Some drugs are used to treat viral infections, but few useful treatments exist because most drugs that destroy viruses also damage the host cell. Both vaccines and treatments for viral infections are properly classified as drugs. The prevalence of upper respiratory tract infections, and the shortage of means to prevent or treat them, point to the desirability of nondrug methods to reduce the risk of infection.

The fact that some drugs are classified as antiviral agents does not mean that all antiviral agents must be classified as drugs. For example, household cleansers make claims to disinfect surfaces, including claims to inactivate viruses. These products perform a useful function in promoting good health, but are not regulated as drugs despite performing a similar function as some drugs. The distinction between product classification and activity can be further illustrated by examining some physiological activities, and considering both drug and nondrug products which perform those activities.

There are many physiological activities which can be accomplished by both drug and nondrug products. FDA has established monographs (final or tentative final) for several categories of over-the-counter (OTC) drug products (final or proposed 21 CFR 330 through 357). Among these categories are the following:

antacids, antiflatulents, laxatives, antidiarrheal products, antiemetics, sleep aids, stimulants, antitussives, expectorants, nasal decongestants, analgesics and antipyretics, digestive aids, anthelmintics, cholecystokinetics, weight control products, deodorants, overindulgence relievers, menstrual products, poison treatments.

These categories were chosen for illustration because they describe body structures and functions, not diseases. It is not difficult to find conventional foods and dietary supplements which affect the same structures and functions. For example, prunes and wheat bran are used as laxatives, coffee and cola beverages are used as stimulants, and there are innumerable foods promoted for weight control. To carry the illustration to an extreme, a beach umbrella performs as a sunscreen, which is another OTC drug category. It would be absurd to regulate these products as drugs.

Clearly, then, there are a variety of body structures and functions which are affected by both drug and nondrug products. The existence of drugs which claim to affect body structure or function does not preclude dietary supplements from claiming the same effects. The real issue is whether or not the claimed effect is a disease.

STRUCTURE/ FUNCTION OR DISEASE

Dietary supplements are allowed to make statements of nutritional support, including statements which describe effect on the structure and function of the body. They are not allowed to claim to cure, prevent, or treat disease. However, even a product which claims only to support healthy body structure and function serves to reduce the risk of disease. A claim to promote good health should not be considered a drug claim, even though the claim implies a reduced risk of disease.

We have examined several of the statements of nutritional support submitted to FDA under the notification requirements of DSHEA. We took special note of the following nine statements because they may help illustrate the distinction between a structure/ function and a disease. We believe that all nine of these statements are appropriate for dietary supplements, and do not constitute drug claims. All of these claims are well accepted by the general public. To the best of our knowledge, none of these statements has provoked a response from FDA that they may be drug claims.

1. Calcium helps build strong bones.
2. Antioxidants help combat free radicals and oxidants, molecules which damage cells and DNA.
3. By inhibiting angiogenesis, [cartilage] may alleviate the discomfort and reduced mobility associated with aging joint conditions, especially those caused by wear and tear.
4. Vitamin E helps prevent oxidation of LDL cholesterol.
5. [Garlic] supports healthy cholesterol levels by reducing serum cholesterol.
6. [Choline] helps in the production of lipotropic agents which convert fats into useful products and in the production of HDL (good) cholesterol.
7. [Echinacea] stimulates the growth of the body's own immune system.
8. Echinacea purpurea helps promote general well being during the cold and flu season.
9. Cranberry fruit inhibits adhesion of E. coli bacteria to the lining of the bladder.

Statement 1 is a conventional claim for an essential mineral nutrient. It implies that an insufficient intake of calcium leads to weak bones. The common perception is that calcium supplementation reduces the risk of osteoporosis.

Statements 2 and 3 describe the effect of these dietary ingredients on body structures and functions. They do not specifically mention any disease. However, a consumer could easily conclude that these products reduce the risk and/or consequences of cancer and arthritis.

Statements 4 through 6 describe the effects of dietary ingredients on cholesterol. Cholesterol is not a disease, but controlling cholesterol is commonly associated with a reduced risk of cardiovascular diseases.

Statement 7 describes the role of the dietary ingredient Echinacea in support of the immune system, while statement 8 indicates diseases where the immune system plays an important role. Neither statement 7 nor 8 specifically states that Echinacea reduces the risk of cold and flu, but this is a reasonable conclusion from these statements.

Statement 9 directly states that the dietary ingredient cranberry prevents the adhesion of bacteria to a body structure. This implies that bacteria are normally present

in the bladder, that the healthy body normally functions to prevent adhesion. The dietary ingredient supports this function, reducing the risk of bladder infection. Note that this statement for cranberry is remarkably similar to the statement for Sambucol "stops viruses in the throat".

It is possible to infer a disease relationship from these, or any, statements of nutritional support. Any mention of a healthy condition implies the existence of a corresponding unhealthy condition. It was clearly not the intent of Congress, in passing DSHEA, to prevent dietary supplements from making any statement which, however remotely, relates to disease. We believe that the best and clearest description of claims allowed for dietary supplements comes from the literal description in DSHEA of claims which are not allowed: "A statement under this subparagraph (§403r6) may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases". All nine of these statements, as well as the statements for Sambucol, are allowed under this description.

CONCLUSION

We conclude that the statement made for Sambucol, "stops viruses in the throat", and similar statements are acceptable for a dietary supplement. This statement does not claim to prevent or treat disease, and specifies the body structure affected. It is not an all-encompassing claim to stop viruses or to restore immunity. It falls readily within the scope of accepted statements made for other nondrug products, including other dietary supplements.

If Sambucol is considered a drug based on this statement, then a variety of useful products would also require regulation as drugs. This level of regulation would unduly impede innovation and product availability, and would be detrimental to public health. Congress found in DSHEA that "promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures". If FDA desires to describe the scope of dietary supplement claims other than by the language of DSHEA, we would like to have a detailed explanation of their description.

Safe and Effective Virus Control

When your family is exposed to airborne viruses, reach for Sambucol.[™]
A breakthrough in herbal science, Sambucol is safe, effective, and
natural. Imported from Israel and patented in the U.S., Sambucol
is available in great tasting syrup and convenient lozenges.

Sambucol stops viruses
in the throat before
they spread.



Derived
from the
juice of black
elderberry, Sambucol has been tested
in laboratory and clinical studies.

SAMBUCOL

*This statement has not been evaluated
by the Food and Drug Administration.
This product is not intended to diagnose,
treat, cure, or prevent any disease.





J.B. Harris, Inc.

*Searching the globe for the
best in alternative healing.*

Safe and Effective Virus Control*

Now that J.B. Harris, Inc. has successfully introduced **Sambucol™** in the United States, many other companies are jumping on the bandwagon by creating their own elderberry products. But did you know that **Sambucol™** is the *only* elderberry product to have been proven effective in laboratory and clinical studies? In fact, virtually all of the elderberry research conducted worldwide has been done on **Sambucol™**!

Sambucol™ is the result of nearly twenty years of research and exhaustive testing in hospital laboratories. Produced by an exclusive *patented* process developed by renowned virologist Dr. Madeleine Mumcuoglu, **Sambucol™** is the *only* elderberry extract to show anti-viral activity in clinical tests. Strict, ongoing quality controls ensure that these anti-viral properties are present in every product bearing the **Sambucol™** name.

Anyone can make claims about the effectiveness of elderberry products, but only Sambucol can back up these claims with clinical research—research validated by millions of consumers worldwide. Completely safe and all natural, Sambucol is available in great tasting syrup or convenient lozenges. Don't accept substitutes or placebos. Insist on *the original* . . . ask for **Sambucol™** by name.

SAMBUCOL™

4324 Regency Drive, Glenview, IL 60025 • (847) 827-8664 • Fax (847) 827-6605

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



Safe and Effective Virus Control*

When your family is exposed to airborne viruses reach for Sambucol™, the original patented Israeli elderberry formula. Sambucol is the *only* elderberry product to have been tested, standardized, and proven effective in laboratory and clinical studies. Completely safe and all natural, Sambucol is available in great tasting syrup and convenient lozenges. Insist on the best. *To order or for more information, call 800-871-1178.*



J.B. Harris, Inc.

Searching the globe for the best in alternative healing.

6324 Regency Drive, Glenview, IL 60025
 (847) 827-8664 • Fax (847) 827-6605

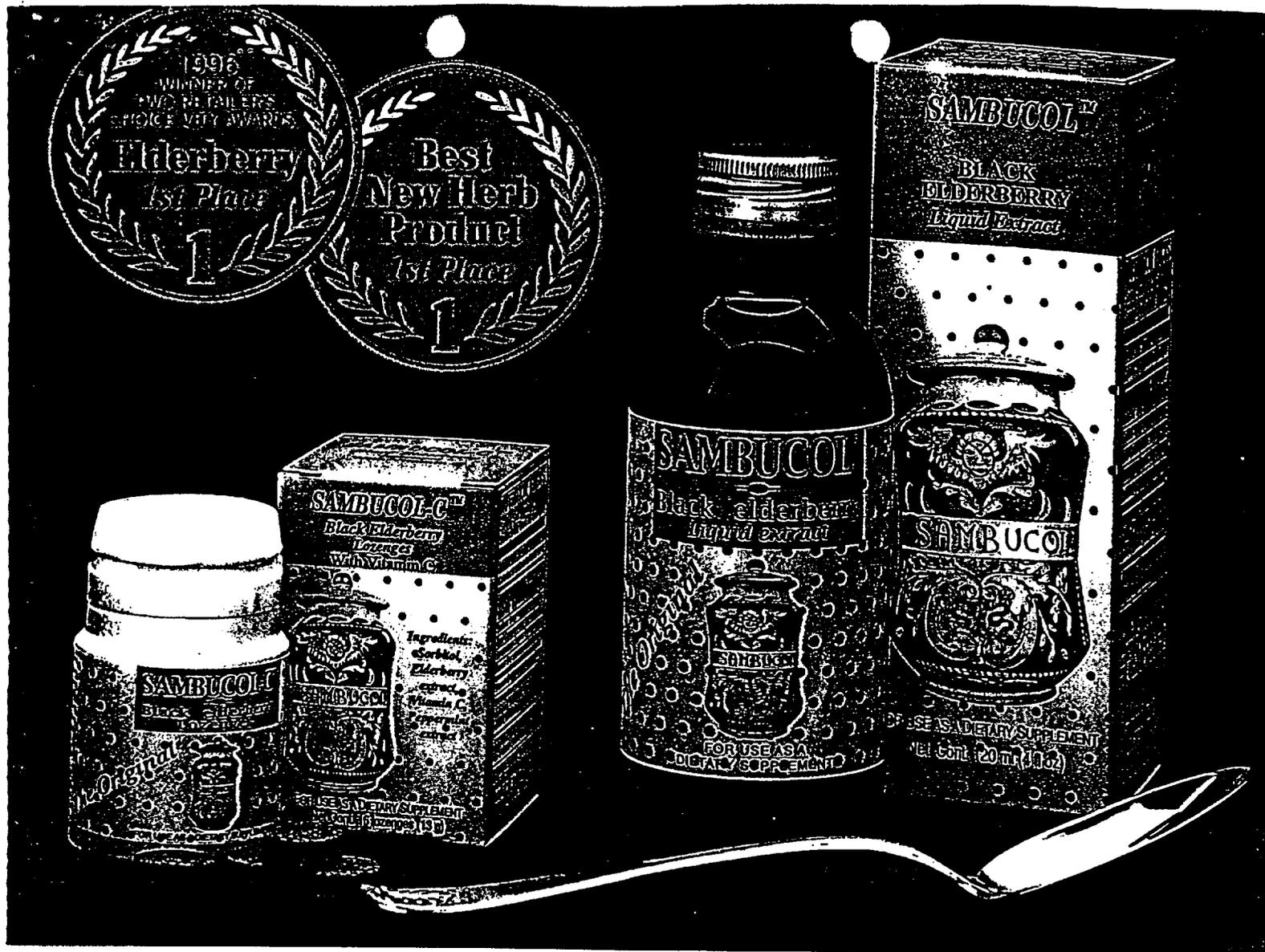
SAMBUCOL™

The #1 choice for Elderberry and Best New Herb Product

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The original patented elderberry formula from Israel

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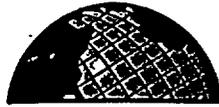
SAMBUCOL™

The #1 choice for Elderberry and Best New Herb Product

SOURCE: VITAMIN RETAILER 1996 VITY AWARDS

The original patented elderberry formula from Israel

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