DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 16 1998 8327 '98 NOV 18 P2:11

Mr. John P. Venardos
Vice President, Regulatory Affairs,
International Product Management
Herbalife International of America, Inc.
9800 La Cienega Boulevard
Inglewood, California 90301

Dear Mr. Venardos:

This is in response to your letter of November 4, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Herbalife International of America, Inc. is marketing the product **Zinc & Echinacea Throat Lozenges** as a dietary supplement. This product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as a dietary supplement. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the dietary, and are labeled as a dietary supplement.

This product is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

> The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...

975-0163

LET 232

> The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, a product taken orally, but that delivers its contents only to the mouth or throat to exert its effect, is not subject to regulation as a dietary supplement because it is not "intended for ingestion." That your product is intended to deliver its contents prior to introduction into the gastrointestinal tract to exert its effect is evidenced by statements in your labels that the lozenges are intended for use as "throat lozenges" and that their use "helps cool and soothe the throat."

Furthermore, the products **Zinc & Echinacea Throat Lozenges** and **Super Echinacea+** appear to bear claims not permitted under 21 U.S.C. 343(r)(6). The products are promoted using the claims "triple protection against seasonal discomforts," "address seasonal discomforts," and "all three products can be combined for maximum relief." The product brochure also promotes these two products as part of a kit, which: (1) includes the product **Herbal Throat Spray**, a homeopathic drug product for the "relieve of sore-throat pain, discomfort or hoarsenesss;" and (2) is promoted for sore throats, colds and flu symptoms.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for the products **Zinc & Echinacea Throat Lozenges** and **Super Echinacea+** suggest that they are intended to treat, prevent, or mitigate disease, namely, sore throats and colds and influenza. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Dorsey)
r/d:HFS-456:RMoore:11/11/98
Init:GCF-1:DDorsey:11/12/98
f/t:HFS-456:rjm:11/13/98:docname:62223.adv:disc33

HERBALIFE

HERBALIFE INTERNATIONAL OF AMERICA, INC
9800 La Cienega Blvd., Inglewood, CA 90301
Mailing Address: P.O. Box 80210, Los Angeles, CA 90080-0210
(310) 410-9600 • FAX: (310) 258-7124

JOHN P. VENARDOS
Vice President, Regulatory Affairs
International Product Management

November 4, 1998

Office of Special Nutritionals (HFS-450)
Center For Food Safety and Applied Nutrition
FOOD & DRUG ADMINISTRATION
200 C Street, S.W.
Washington, D.C. 20204

RECEIVED 11/10/98

Ref.: **Zinc & Echinacea Throat Lozenges Dietary Supplement**

Dear Sir and/or Madam:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. has begun commercializing Zinc & Echinacea Throat Lozenges dietary supplement in the United States.

Zinc & Echinacea Throat Lozenges is labeled and promoted with statements provided for in section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

LABEL
Dietary Supplement.
Zinc & Echinacea Throat Lozenges are a synergistic blend of Zinc, high-quality Echinacea, Slippery Elm extract and menthol to help promote seasonal health.

MINI PRODUCT BROCHURE LITERATURE
Healthy throat formula.
Our new Zinc & Echinacea Throat Lozenge is a synergistic blend of Zinc, high-quality Echinacea, Slippery Elm extract and soothing Menthol. Studies suggest that Zinc, an essential trace mineral, can help support the immune system. The herb, Echinacea, has been used for centuries as a natural way to promote good health. The gentle and effective herb, Slippery Elm, is known for its soothing properties.

- Includes Echinacea, an herb known for its immune-supporting actions.
- Contains Zinc, an essential mineral that helps keep the body's enzyme systems healthy.
- Includes Menthol, which helps cool and soothe the throat.
- Pleasant-tasting lemon flavor lozenge is convenient to use.

FACT SHEET
Description:
Dietary supplement for a healthy throat.

Features	Benefits:
Echinacea	An herb known for its immune-supporting actions. Used by Native Americans to promote well-being.
Zinc	An essential mineral that helps keep the body's enzyme systems healthy.
Slippery Elm	A gentle and effective herb known for its soothing properties.
Menthol	Helps cool and soothe the throat.

***HERBALIFE TODAY* NEWSLETTER**

Dietary supplement for a healthy throat.

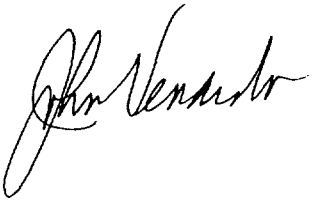
- Includes Echinacea, an herb known for its immune-supporting actions.
- Contains Zinc, an essential mineral that helps keep the body's enzyme systems healthy.
- Great tasting honey-lemon flavor.

Product labeling prominently bears the required boxed statement, "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

Herbalife International of America, Inc. certifies that the information contained in this notice is complete and accurate, and that the Company has substantiation that the foregoing statements are truthful and not misleading.

Please do not hesitate to advise should you have any questions.

Sincerely,



File: **Zinc & Echinacea Throat Lozenges Dietary Supplement**

Zinc & Echinacea Throat Lozenges Honey Lemon Flavor Dietary Supplement

Supplement Facts

Serving Size: 1 lozenge
Servings Per Container: 18

	Amount per Serving	%Daily Values*
Calories	15	
Total Carbohydrate	4g	1%
Sugar	3g	
Zinc	10 mg	67%
Dried Echinacea Extract (4:1 Echinacosides) (Echinacea angustifolia) (root)	15 mg	†
Slippery Elm Extract (1:1 in edible ethanol) (Ulmus fulva) (bark)	15 mg	†

* Percent Daily Values are based on a 2,000 calorie diet
† Daily Value not established

Other Ingredients: Honey, Citric Acid, Malic Acid, Artificial Honey Flavor, Natural Lemon Flavor, Acesulfame Potassium and Menthol.

Zinc & Echinacea Throat Lozenges are a synergistic blend of zinc, high-quality Echinacea extract, Slippery Elm extract and menthol to help promote seasonal health.

Suggested Serving: Take one Zinc & Echinacea Throat Lozenge every 3 to 4 hours. In order to avoid nutritional imbalance, do not exceed six lozenges per day for 3 consecutive days.

Herbalife products are available only through Herbalife Independent Distributors.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

30-day money back guarantee.

Formulated Exclusively for:
HERBALIFE INTERNATIONAL OF AMERICA, INC.
105 ANGELES, CA 90080-0210, U.S.A.

MADE IN U.S.A.

Individually wrapped for safety, convenience and to ensure freshness

Zinc & Echinacea Throat Lozenges Honey Lemon Flavor Dietary Supplement

HERBALIFE®

Zinc & Echinacea Throat Lozenges

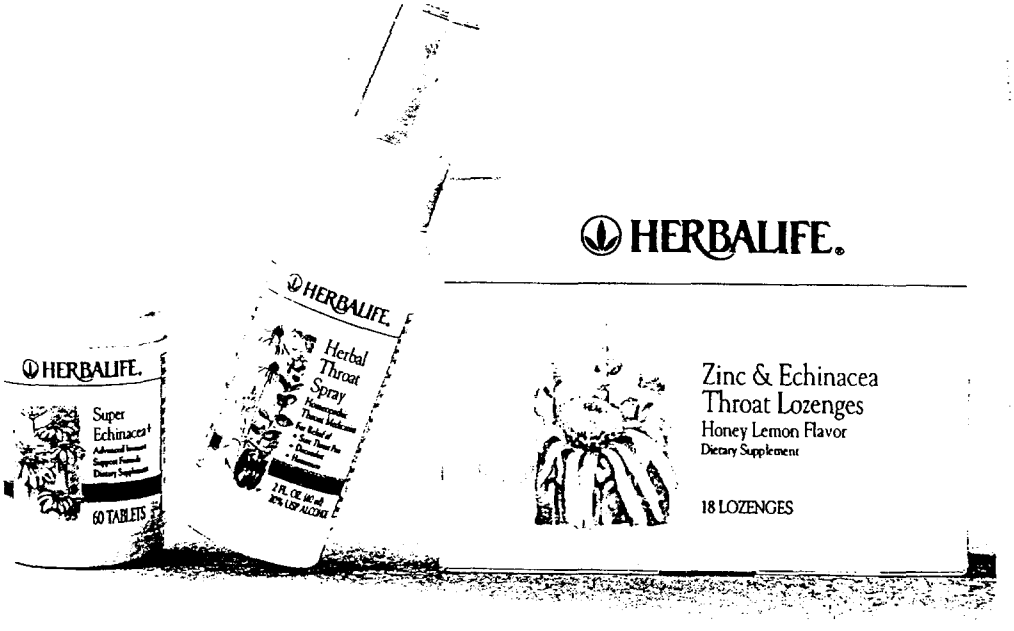
Honey Lemon Flavor

Dietary Supplement

18 LOZENGES

IMMUNE-SUPPORT KIT

Triple protection against seasonal discomforts.



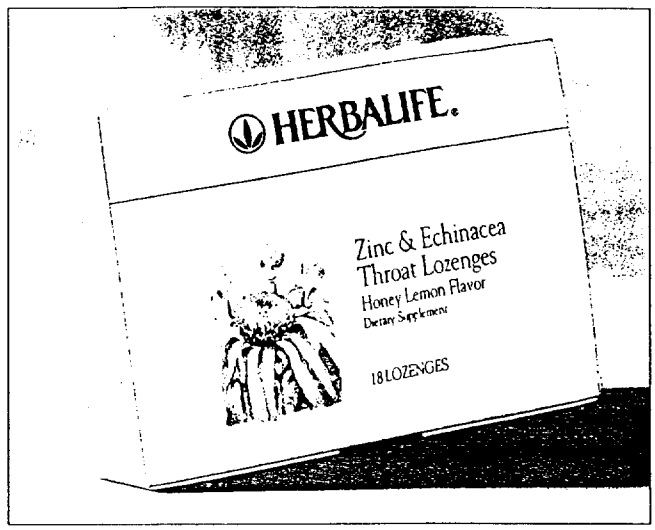
Zinc & Echinacea Throat Lozenges • Super Echinacea + • Herbal Throat Spray

Zinc & Echinacea Throat Lozenges, Super Echinacea + and Herbal Throat Spray are combined in a convenient kit. Formulated from a blend of time-honored herbal ingredients, these advanced products reflect Herbalife's belief that the best way to address seasonal discomforts is the natural way.

- Zinc & Echinacea Throat Lozenges and Super Echinacea + include a powerful blend of carefully selected herbal ingredients that promote good health.
- Herbal Throat Spray temporarily eases sore throat pain, discomfort or hoarseness.
- All three products can be combined for maximum relief.
- Spray, lozenges and tablets are easy to use and can be taken anywhere.

$29.85
#2009
#0239 (HAP or unit)

HERBALIFE®
Fact Sheet



PRODUCT NAME:	Zinc & Echinacea Throat Lozenges
SKU #:	1135 (case) 0208 (HAP or unit)
RETAIL PRICE:	U.S. $5.95 (each)
VOLUME POINTS:	4.70
SIZE:	18 lozenges per box
PACKAGING:	6 boxes per case
DESCRIPTION:	Dietary supplement for a healthy throat.
FEATURES:	**BENEFITS:**
Echinacea	An herb known for its immune-supporting actions. Used by Native Americans to promote well-being.
Zinc	An essential mineral that helps keep the body's enzyme systems healthy.
Slippery Elm	A gentle and effective herb known for its soothing properties.
Menthol	Helps cool and soothe the throat.
USER:	Adults
USAGE:	Take one lozenge every three to four hours. Do not exceed six lozenges per day.
CROSS-SELL:	Zinc & Echinacea Throat Lozenges can be used in conjunction with the Thermojetics® Weight-Management Program and Herbalife's entire line of nutritional products.
COLLATERAL MATERIAL:	*New Products Brochure*

NEW PRODUCT

GA-095

US Edition No. 049

HERBALIFE.

TODAY

NEWS FOR BUSINESS BUILDING

"I don't encounter obstacles in life. I prefer to think of them as challenges."

—Mark Hughes

Five New Herbal-Based Products

continued from page 1

throats, cold and flu symptoms. And we've made it easy for customers to triple their health protection with our Immune-Support Kit, which combines Zinc & Echinacea Lozenges, Super Echinacea + and Herbal Throat Spray in one convenient package.

Get familiar with these products so you can share them with customers and prospects. Winter is quickly approaching, which makes this the ideal time to let everyone know about our new seasonal product line. So get the word out—and you'll see a healthy return on your efforts!

Zinc & Echinacea Throat Lozenges

Dietary supplement for a healthy throat.

- Includes Echinacea, an herb known for its immune-supporting actions.
- Contains Zinc, an essential mineral that helps keep the body's enzyme systems healthy.
- Great tasting honey-lemon flavor.
  #1135 (case of 6) $5.95
  #0208 (HAP or unit)

Super Echinacea +

Immune-support formula.

- Contains carefully selected herbs that may help you feel better and may help support your immune system.
- Includes Echinacea Extract, a North American herb used by Native Americans to promote well-being.
  #1523 (case of 6) $16.95
  #0207 (HAP or unit)

Herbalife continues to provide products that help fight common health concerns and also improve the lives of customers, and move your business forward.

Herbal Throat Spray

Homeopathic Throat Medication.

- This therapeutic product is formulated with ingredients that are listed in the homeopathic pharmacopoeia.
- Includes a powerful blend of Echinacea, Kava Kava, Thyme and Club Moss.

- Temporarily eases sore-throat pain, discomfort or hoarseness.
- Cool peppermint flavor.
- Convenient spray applicator.
  #3048 (case of 6) $6.95
  #0211 (HAP or unit)

Immune-Support Kit

Triple protection against seasonal discomforts.

- Includes Zinc & Echinacea Throat Lozenges, Super Echinacea + and Herbal Throat Spray in a convenient kit.
- Contains a powerful blend of carefully selected herbal ingredients that may help you feel better.
- Temporarily eases sore throat pain, discomfort or hoarseness.
  #2009 (case of 6) $29.85
  #0239 (HAP or unit)

Complementing our seasonal line, we've formulated additional products that are inspired by Mother Nature and include ingredients that are renowned for their health benefits.

Mega Garlic Plus

A dietary supplement.

- Derived from the world's best garlic.
- Includes a synergistic selection of herbs that complement garlic's healthy actions.
- Has no aftertaste.
  #3050 (case of 6) $18.95
  #0212 (HAP or unit)

K8

Nature's relaxation formula.

- A combination of natural herbs, including Kava Kava and Ashwagandha, an Ayurvedic herb designed to help relax the body and increase your feelings of well-being.
- Each serving contains 150 mg of Calcium to help build strong bones.
- Includes Bio-Absorption Complex-5, which helps the body absorb the beneficial properties of the herbs.
  #3051 (case of 6) $13.95
  #0213 (HAP or unit)