DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 19 2001

Ms. Eleanor F. Barbo
Senior Director
Regulatory Affairs
Whitehall-Robins Healthcare
Five Giralda Farms
Madison, New Jersey 07940

Dear Ms. Barbo:

This is in response to your letter to the Food and Drug Administration (FDA), dated October 2, 2001, 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 Whitehall-Robins Healthcare is making the following claim, among others, for the product **Robitussin Sunny Organe Vitamin C Supplement Drops:**

"...soothe your throat."

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.

An article that is delivered orally, but that exerts its effect prior to being swallowed (for example, a drop or lozenge that is intended to soothe the throat) 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:

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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.").

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 that is intended to have its effect before it is ingested is not subject to regulation as a dietary supplement because it is not "intended for ingestion" and is a drug under 21 U.S.C. 321(g)(1)(C) because it is an article (other than food) intended to affect the structure or function of the body.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
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, New England District Office, Compliance Branch, HFR-NE240

Eleanor F. Barbo
Senior Director, Regulatory Affairs

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WHITEHALL ROBINS

October 2, 2001

Robitussin® Sunny Orange Vitamin C Supplement Drops

Notification of Statements on Dietary Supplement Labels

Dr. Robert Moore, Branch Chief
Dietary Supplement Branch (HFS-811)
Division of Compliance and Enforcement
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204

Dear Dr. Moore:

Reference is made to Robitussin® Sunny Orange Vitamin C Supplement Drops, marketed by Whitehall-Robins Healthcare, ("Whitehall-Robins"), a division of American Home Products Corporation.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. §343(r)(6), notification is submitted for structure/function statements made on the following dietary supplement product.

Product Name:	Robitussin Sunny Orange Vitamin C Supplement Drops
Ingredients:	Vitamin C 60 mg (as sodium ascorbate and ascorbic acid)
Company Name/ Address:	Whitehall-Robins Healthcare Five Giralda Farms Madison, NJ 07940-0871

Statements on the Package Label:

1. Front Panel
   - Helps support immune system*

2. Back Panel
   - A great tasting and convenient way to help support your immune system* and soothe your throat.

In accord with 21 CFR §101.93, the disclaimer statement is bolded and boxed on all panels of the package label where structure/function claims appear.

The undersigned certifies that the information contained in this notice is complete and accurate, and that Whitehall-Robins has substantiation that the statements made are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (973) 660-5751.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE

Eleanor F. Barbo
Senior Director
Regulatory Affairs