



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

November 28, 2000

James T. Tanner, Ph.D.
Executive Vice President of Science
Food Research, Inc
328 N. College Street
Harrodsburg, KY 40330

Dear Dr. Tanner:

This responds to your inquiry of November 8, 2000, requesting our comments on the product CitroBio. In the letter, you indicate that your client, CitroBio, Inc (bearing the same name as the product) has authorized you to reformulate and resubmit the information concerning this product to FDA. You describe the manufacturing process of CitroBio and its intended use. You state that because all of the ingredients in CitroBio are generally recognized as safe (GRAS), the product itself is GRAS.

Based on the information you provided, CitroBio is a diluted aqueous solution of the filtrate of a homogeneous mixture deriving from whole oranges, glycerin, citric acid and alpha-tocopherol. During the manufacturing of CitroBio, only low heat is applied to the mechanically compressed oranges, which is then followed by addition of the other three ingredients under a specific order and specific conditions. CitroBio is intended for use as an antimicrobial for washing fruits, vegetables and seafood.

GRAS status in general refers to food ingredients, rather than to food products. A food product is considered legal if all of its ingredients are GRAS or approved food additives. Because all of the ingredients that make up CitroBio are GRAS, the product CitroBio made in the manner as described in your letter would be legal under the current FDA regulations for its intended use, provided that the product is effective as an antimicrobial for such use.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Lawrence J. Lin, Ph.D.
Division of Petition Control, HFS-215
200 C Street, S.W.
Center for Food Safety
and Applied Nutrition