FEDERAL TRADE COMMISSION

[File No. 992 3027]

Efamol Nutraceuticals, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before June 12, 2000.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Matthew Gold or Linda Badger, Federal Trade Commission, Western Region, 901 Market St., Suite 570, San Francisco, CA 94103. (415) 356–5276 or 356–5275.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for May 11, 2000), on the World Wide Web, at ''http://www.ftc.gov/ftc/formal.htm.'' A paper can be obtained from the FTC Public Reference Room, Room H–130, 600 Pennsylvania Avenue, NW, Washington, DC 20580, either in person or by calling (202) 326–3627.

Public comment is invited. Comments should be directed: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW, Washington, DC 20580. Two paper copies of each comment should be filed, and should be accompanied, if possible, by a 3½ inch diskette containing an electronic copy of the comment. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Efamol Nutraceuticals, Inc., (''Efamol''). Efamol is a marketer of dietary supplement products, all of which contain essential fatty acids.

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves alleged misleading representations for Efalex and Efalex Focus, two of Efamol's dietary supplement products. The advertisements claimed that these products can mitigate or cure the effects of Attention Deficit Disorder or Attention Deficit Hyperactivity disorder (''ADD/ADHD'').

The proposed complaint alleges that Efamol could not substantiate the following claims: (1) The Efalex and Efalex Focus can cure, prevent, treat or mitigate ADD/ADHD or its symptoms; and (2) that Efalex and Efalex Focus are effective in reducing attention and behavioral problems. Part I of the proposed order would address these misrepresentations by prohibiting Efamol from making the claims in the future unless it possesses and relies upon competent and reliable scientific evidence that substantiates the claim.

Part II of the proposed order requires Efamol to possess competent and reliable scientific evidence for any claim about the health benefits, efficacy or safety of any food, drug or dietary supplement that contains essential fatty acids. Because all of Efamol's products contain essential fatty acids, this provision would apply to the company's entire current product line.

Part III of the proposed order contains language permitting Efamol to make drug claims that have been approved by the FDA pursuant to either a new drug application or a tentative final or final standard. Part IV states that Efamol would be permitted to make claims that the FDA has approved pursuant to the futuT*rp Patedard. Part Ir1 -s suilfamol from mages tiion the s pr