UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF THE SECRETARY

July 23, 2002

Enforma Natural Products, Inc.
through their counsel
Edward F. Glynn. Jr., Esquire
VENABLE BAETJER HOWARD & CIVILETTI, LLC
1201 New York Ave., N.W., Suite 1000
Washington, D.C. 20005-3917

Re: Petition of Enforma Natural Products, Inc. to Limit
Civil Investigative Demand – File No. X000069

Dear Mr. Glynn:

This letter advises you of the Federal Trade Commission's ruling on the above-referenced Petition to Limit ("Petition"). The decision was made by Commissioner Sheila F. Anthony, acting as the Commission's delegate. See 16 C.F.R. § 2.7(d)(4).

The Petition is **denied** for the reasons stated below. The new deadline for Enforma Natural Products, Inc. ("Enforma") to respond to, and otherwise comply with, the Civil Investigative Demand ("CID") is **Friday, August 2, 2002.**

Enforma has the right to request review of this matter by the full Commission. Such a request must be filed with the Secretary of the Commission within three days after service of this letter ruling. The filing of a request for review by the full Commission does not stay or otherwise affect the new return date – August 2, 2002 – unless the Commission rules otherwise. See 16 C.F.R. § 2.7(f).

I. BACKGROUND

In the Spring of 2000, the FTC simultaneously filed a complaint and stipulated final order of settlement (the "Order") against Enforma in the United States District Court for the Central District of California. See *FTC v. Enforma Natural Products, Inc., et al.*, CV 04376-JSL (CWx) (C.D. Cal.). The Commission's complaint alleged that defendants made false and unsubstantiated weight loss claims for two dietary supplements – "Fat Trapper" and "Exercise In A Bottle" – in two infomercials. Along with requiring the payment of $10 million in consumer redress, the Order (1) prohibits the defendants from making unsubstantiated claims that any product, service or program causes or maintains weight loss or avoids weight gain without

dieting or exercise, prevents fat absorption, increases metabolism, burns fat, or allows weight loss even if users eat high fat foods; (2) requires the defendants to include with future weight loss claims a clear and prominent disclosure that reducing calorie intake and/or exercising more is necessary to lose weight; (3) requires the defendants to have scientific substantiation for any claims about the health or weight loss benefits, performance, safety or efficacy of any product, service or program; and (4) prohibits the defendants from making false claims about the existence or results of any tests, studies or research.

In addition, the Order specifically authorizes the Commission to monitor Enforma's compliance by all lawful means, including compulsory process.[1] The CID at issue here is part of such a compliance monitoring effort. The FTC's concerns about Enforma's compliance began in 2001, when the Commission learned that the two dietary supplements at issue in the suit were still being advertised. In January, 2002, the Commission filed an application for an order to show cause why Enforma should not be held in contempt for violating the final order. That application is presently pending before the court.

In the Spring of 2002, the FTC learned of two new Enforma infomercials being broadcast on television promoting three weight loss products: Carb Trapper Plus, Acceleron, and Chitozyme. Carb Trapper Plus and Acceleron were also being promoted extensively on Enforma's website and sold at retail under Enforma's name. The FTC began an investigation to determine whether the advertising and sale of these products was in compliance with the Order. In response to requests from staff beginning on May 15, 2002, Enforma submitted copies of advertisements and purported substantiation for certain claims for these products including portions of a clinical study that Enforma had commissioned William V. Judy, PhD to conduct. Commission staff requested, but was refused, certain additional data pertaining to the study. On June 11, 2002, the Commission issued a CID to Enforma requesting the underlying Carb Trapper Plus data; documents relating to any terms of employment or consulting relationship between Dr. Judy and Enforma; and documents relating to any communications between Dr. Judy and Enforma.[2]

On June 24, 2002, Enforma filed its Petition to Limit. Enforma claims that the requests contained in the CID would require the production of certain documents relating to a second study conducted by Doctor Judy for a product that has not yet been advertised or marketed. Enforma argues that the Commission cannot properly require production of this material because the FTC's investigative power does not extend to possible future violations. It asks that the

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[1] Stipulated Final Order ¶ XIV.B.

[2] See, FTC "Resolution Directing Use of Compulsory Process in a Nonpublic Investigation of Advertisers and Marketers of Dietary Supplements and Unnamed Others." issued September 2, 1999 ("Resolution").

Commission, therefore, limit the "CID so as to exclude documents unrelated to [the Carb Trapper Plus study] which relate only to the analysis by Doctor Judy of the product that has neither been advertised nor sold . . . ." Petition at 3.

Commissioner Anthony carefully reviewed the Petition and determined that it should be denied for the reasons set forth below.

II. ANALYSIS

The Commission has broad powers to obtain relevant information through compulsory process. As the Supreme Court stated more than fifty years ago, "it is sufficient if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant." *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950). The CID at issue here meets all three of these criteria.

At base, the Petition questions the Commission's *authority* to obtain the withheld documents as well as their *relevance* to the Commission's investigation. The Commission's authority to investigate the potentially false or deceptive marketing of Enforma's dietary supplements – Carb Trapper Plus, Acceleron, and Chitozyme – is beyond dispute.[3] As such, Enforma resorts to mischaracterizing the investigation as one aimed as at uncovering potential future violations in connection with a product presently undergoing testing but that has yet to be advertised or marketed. The Commission is doing no such thing.

Petitioner's argument boils down to this: the Commission cannot properly investigate potential *future* violations; the materials relating to Doctor Judy's latest study are for a product that has not yet been advertised or marketed; and, therefore, the Commission cannot properly obtain these materials, as no violation could yet have occurred with respect to the new product. Even assuming for the sake of argument that the Commission cannot investigate potential future violations in the consumer protection context,[4] and where the issue is monitoring of compliance

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[3] The Resolution authorizing the use of compulsory process here defines the nature and scope of the investigation as: "to investigate the marketing of dietary supplements, for the purpose of determining whether unnamed persons, partnerships, or corporations, or others engaged in the advertising and marketing of dietary supplements have misrepresented or are misrepresenting the safety or efficacy of their products or services . . . ." FTC "Resolution Directing Use of Compulsory Process in a Nonpublic Investigation of Advertisers and Marketers of Dietary Supplements and Unnamed Others." issued September 2, 1999 (File No. 992 3267).

[4] Petitioner cites a 1965 case arising under the Antitrust Civil Process Act, a statue similar to the portions of the FTC Act authorizing the Commission's use of CIDs, 15 U.S.C. § 57b-1, where a CID issued by the U.S. Department of Justice in an effort to investigate proposed acquisitions by fertilizer companies of petroleum companies was set aside on the ground that "the definitions of 'antitrust

with a standing court order (as opposed to a *de novo* investigation), Petitioner's argument still fails because the documents the Commission seeks are relevant to its ongoing investigation of potential past and present violations relating to products that are being and have been advertised and sold, namely: Carb Trapper Plus, Acceleron, and Chitozyme.

It is a petitioner's burden to show that the information sought through administrative compulsory process is irrelevant. *Invention Submission Corp.*, 965 F.2d 1086, 1090 (D.C. Cir. 1992), *cert. denied,* 507 U.S. 910 (1993). Enforma has utterly failed in this regard. As explained above, rather than present evidence that categories of documents sought or the documents being withheld are not relevant, it chose to attempt to recast the Commission's investigation.

The documents relating to Doctor Judy's study of the yet-to-be-marketed product are relevant to the ongoing investigation of Carb Trapper Plus, Acceleron, and Chitozyme. Among other things, the new product may use the same ingredients or the same mechanism of action (*e.g.*, trapping fat, increasing metabolism, or decreasing appetite) as the products under investigation. Likewise, a comparison of the study protocols used in each instance may be revealing. Further, the documents may have the potential to impeach Doctor Judy or reveal potential bias. This is by no means an exhaustive list, but rather is included merely to demonstrate some of the myriad ways that the documents sought through the CID, including the documents relating to the new study, are plainly relevant to the ongoing investigation of the products Enforma is presently marketing.

Thus, Enforma is essentially arguing for a rule that any documents relating to products in development are somehow exempt from disclosure and need not be produced even though those documents may be entirely relevant to issues involved in the investigation of products that *have* been brought to market. This argument is absurd; no such blanket exemption exists, nor could it.

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investigation' and 'antitrust violation' in the ACPA refer to ongoing and past, but do not include possible future, antitrust violations." *Australia / Eastern U.S.A. Shipping Conference v. U.S.*, 1981 WL 2212, *5 (D.D.C. 1981) summarizing *U.S. v. Union Oil of Cal.*, 343 F.2d 29, 30-31 (9th Cir. 1965). Notably, the *Union Oil* case predates the Hart Scott Rodino Act of 1976 by eleven years. Similar pre-merger investigations of "possible future antitrust violations" are now routine and explicitly authorized by law.

Moreover, the portion of the FTC Act analogous to the ACPA paragraph at issue in the *Union Oil* case, 15 U.S.C. 1312(a) (as it existed in 1963), does not require CIDs to be relevant to an "investigation" which, in turn, is limited by statutory definitions to past or present violations, but rather to "unfair or deceptive acts or practices in or affecting commerce" without temporal limitation. 15 U.S.C. § 57b-1(c)(1). This makes sense as the Commission may encounter situations that must be halted in their incipiency under Section 5 before the harm can materialize. This would be particularly important in the dietary supplement area, for example, where products in development might pose health and safety threats or where a company has a demonstrable history of continuing to deceptively market identical compounds under different names.

In sum, the Commission is not investigating potential future violations here; it is investigating past and present violations, and that investigation will likely be informed by documents relating to the product that has yet to be marketed. The documents must be produced.

III. CONCLUSION

For all of the foregoing reasons, the Petition is **denied**, and, pursuant to Rule 2.7(e), 16 C.F.R. § 2.7(e), Petitioners are directed to comply with the Civil Investigative Demand on or before **Friday, August 2, 2002.**

By direction of the Commission.

Benjamin I. Berman
Acting Secretary