Responses to Petitions to Quash

WELLNESS SUPPORT NETWORK

FTC File No. 072 3179 Decision, October 25, 2007

RESPONSE TO PETITION TO QUASH CIVIL INVESTIGATIVE DEMAND

Dear Mr. Fuerst:

This letter advises you of the disposition of the Petition to Quash Civil Investigative Demand ("Petition to Quash") served on Wellness Support Network (hereinafter "Petitioner" or "WSN") in conjunction with an investigation of WSN's conduct by the Federal Trade Commission (hereinafter "FTC" or "Commission"). The Petition to Quash is denied for the reasons hereinafter stated. The new date for Petitioner to comply with the Civil Investigative Demand is November 5, 2007.

This ruling was made by Commissioner Pamela Jones Harbour, acting as the Commission's delegate. *See* 16 C.F.R. § 2.7(d)(4). Petitioner 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.[1]

I. Background and Summary

On July 27, 2007, the Commission issued a Civil Investigative Demand ("CID") to Petitioner in connection with the Commission's investigation into advertising claims made by WSN regarding WSN® Diabetic Pack and WSN® Nerve Support Formula (hereinafter "WSN's products"). Petition at 5. The CID was issued pursuant to the Commission's Resolution of May 12, 2006. *See*

[1] This letter decision is being delivered by facsimile and express mail. The facsimile copy is being provided as a courtesy. Computation of the time for appeal, therefore, should be calculated from the date you received the original by express mail.

Petition, Exhibit G. On August 27, 2007, WSN timely filed its Petition to Quash.

Petitioner claims that the CID should be quashed for three reasons: (1) the FTC "has neither the authority nor the expertise to make a determination as to whether a product is a drug, medical food or a dietary supplement;" Petition at 4; (2) "the CID was not properly tailored to yield information that is relevant and material to this request for information;" *id*. at 9; and (3) the "CID is unreasonably overbroad and unduly burdensome," *id*.

II. The FTC Has Jurisdiction to Investigate Petitioner's Advertising Claims.

This Petition to Quash proceeds from an irrelevant distinction, between medical foods and dietary supplements, to the unsupported conclusion that the FTC lacks the jurisdiction to investigate Petitioner's advertising claims for its products. Section 5 of the FTC Act, 15 U.S.C. § 45, authorizes the FTC to prohibit "unfair or deceptive acts or practices in or affecting commerce." Further, Section 12(a) of the FTC Act, 15 U.S.C. § 52(a), declares unlawful the dissemination of "any false advertisement . . . by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics." WSN provides no cogent reason why its products are excluded from the FTC's jurisdiction.

WSN's reliance on the Memorandum of Understanding ("MOU") between the FTC and the Food and Drug Administration ("FDA"), Petition at 9, is wholly misplaced. On its face, the MOU states that the FTC has "primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs [other than prescription drugs], devices and cosmetics." FDA MOU number 225-71-8003. WSN's claim that its products are medical foods within the meaning of Section 5(b) of the Orphan Drug Act, 21 U.S.C. § 360ee(b)(3), Petition at 7, does not

include any citation of authority that would oust the FTC's jurisdiction under Section 12(a) of the FTC Act over "foods, drugs, devices, services, or cosmetics." WSN's reliance on the MOU is further misplaced in that the FTC cannot by agreement with the FDA abandon jurisdiction bestowed on the FTC by Congress.

The Petitioner has "the burden of showing that an agency subpoena is unreasonable . . . and, where, as here, the agency inquiry is authorized by law and the materials sought are relevant to the inquiry, that burden is not easily met." *Securities and Exchange Commission v. Brigadoon Scotch Distributing Co.*, 480 F.2d 1047, 1056 (1973), *cert. denied*, 415 U.S. 915 (1974). This is especially so in light of the breadth of inquiry this Commission is permitted to conduct. *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950) ("[I]t 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."). WSN did not provide sufficient factual or legal support for its claim that the FTC lacks jurisdiction to investigate WSN's advertisements, nor has it given the Commission any reason to believe that the public interest would be served by failing to exercise its jurisdiction to investigate WSN's advertising claims.[2] WSN's jurisdictional challenge to this CID must, therefore, be denied.

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[2] The Commission may consider a jurisdictional challenge to its compulsory process during the course of an investigation on policy grounds even when such a challenge in the federal courts would not be appropriate. "With rare exceptions (none of which applies here), a subpoena enforcement action is not the proper forum in which to litigate disagreements over an agency's authority to pursue an investigation." *Federal Trade Commission v. Roberts*, 276 F.3d 583, 584 (D.C. Cir. 2001) ("Whatever the merit of Ken Roberts' preemption argument – and we believe they have little – appellants cannot overcome the long-standing doctrine that precludes courts from entertaining challenges to the jurisdiction of administrative agencies during subpoena enforcement proceedings."). "An agency's investigations should not be bogged down by premature challenges to its regulatory jurisdiction." *Federal Trade Commission v. Swanson*, 560 F.2d 1, 2 (1st Cir. 1977); *see Federal Trade Commission v. Monahan*, 832 F.2d 688, 689 (1st Cir. 1987) ("We, like the FTC, must wait to see the results of the investigation before we know whether, or the extent to which, the activity falls within the scope of a [particular defense].").

III. The Information Sought Is Within the Scope of the Resolution/Investigation.

The scope of the investigation is defined by the resolution authorizing the use of compulsory process. The Petitioner mischaracterizes the resolution authorizing staff's use of compulsory process, Resolution of May 12, 2006 attached to the Petition to Quash as Exhibit G, when it claims that

> The Commission is looking for information as it pertains to the advertising of a dietary supplement, and has improperly applied the standard for evaluating dietary supplements to the initial phase investigation conducted prior to the issuance of the CID. As such, it is clear that this investigation is premised on an erroneous conclusion and, therefore, cannot reasonably be tailored to yield information that is relevant or material to the investigation.

Petition at 9. Again, the distinction between dietary supplements and medical foods has no bearing on whether the information required in response to the CID is relevant to the scope of investigation authorized by the resolution. The Resolution defines the scope of the inquiry to include determining "whether unnamed persons . . . engaged directly or indirectly in the advertising or marketing of drugs, devices, dietary supplements or *any other product or service intended to provide a health benefit or to affect the structure or function of the body* have misrepresented or are misrepresenting the safety or efficacy of such products. . . ." Resolution of May 12, 2006 (emphasis supplied). Petitioner admits that its products fit the above description of the Resolution. Petition at 3 ("WSN . . . is in the business of marketing and selling medical foods designed to provide nutrients for the dietary management of Type II diabetes and neuropathy."). The specifications of the CID are relevant to determining whether WSN has misrepresented the safety or efficacy of its products. Petitioner has not demonstrated that any information sought by the CID is legitimately beyond the

scope of this investigation. In fact, the Commission finds that the materials sought by the CID are relevant to the scope of this investigation. Accordingly, the Petition to Quash on the ground that the CID seeks information not relevant to the investigation must be denied.

IV. The Petition Does Not Show that the CID Is Unduly Burdensome.[3]

Allegations of burden must be supported with specificity. *National Claims Service, Inc., Petition to Limit Civil Investigative Demand*, 1998 FTC LEXIS 192, *8 (FTC 1998) ("At a minimum, a petitioner alleging burden must (i) identify the particular requests that impose an undue burden; (ii) describe the records that would need to be searched to meet that burden; and (iii) provide evidence in the form of testimony or documents establishing the burden (e.g., the person-hours and cost of meeting the particular specifications at issue). Petitioner has failed to do any of these things."). Likewise, Petitioner has failed to do any of these things with any reasonable degree of specificity.

The Petition is supported by an Affidavit from Robert Held, Petition, Exhibit J, which claims in summary fashion that the records sought are voluminous, Aff. ¶ 4, that Held (the CEO of WSN) and his daughter, Robyn Held, are the only two of the firm's eleven employees who are capable of preparing the response to the CID, Aff. ¶¶ 4, 6-7, and that compliance would make them otherwise unavailable for some unknown period of time to the detriment of the firm. Aff. ¶¶ 6-7. The Petition, including the Affidavit of Held, does not satisfy Petitioner's burden of demonstrating that compliance would impose an unreasonable burden on WSN. The Commission, therefore, finds that the burden of complying with the

[3] Petitioner's argument that the CID is overbroad was wholly redundant with its argument that the CID sought information not relevant to the investigation and need not be addressed again here.

CID does not appear unreasonable on this record. *See Federal Trade Commission v. Rockefeller*, 591 F.2d 182, 190 (2nd Cir. 1979).

Counsel for WSN makes a further argument that compliance with the CID might result in WSN losing its suppliers of needed materials and products. Petition at 10. This argument is supported by no factual materials. It is claimed that WSN uses vitamins and minerals manufactured "under an exclusive proprietary process" by "a small group of suppliers." *Id.* It is not clear, however, if the proprietary process at issue is that of WSN or of its suppliers. It is further argued that WSN is one of its suppliers' smallest customers and that, therefore, the disclosure of information[4] about this proprietary process creates a "high probability" that the suppliers will cease doing business with WSN and that WSN will be unable to find alternative suppliers – failing which it will cease business operations. Petition at 10. This claim is too speculative and unsupported to serve as the basis for relief.[5]

V. CONCLUSION AND ORDER

For all the foregoing reasons, **IT IS ORDERED THAT** the Petition to Quash filed by Petitioner be, and it hereby is, **DENIED**. Pursuant to Rule 2.7(e), the new date for Petitioner to comply with the CID is November 5, 2007.

By direction of the Commission.

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[4] If information regarding this proprietary process is in fact confidential, then such information should be designated confidential when submitted. Commission staff are bound to comply with set procedures regarding materials so designated. *See generally*, 16 C.F.R. §§ 4.9-4.11. Petitioner provides no evidence that the confidentiality protections provided by 15 U.S.C. § 57b-2 are inadequate to protect this information.

[5] *See Federal Trade Comm. v. Standard American, Inc.*, 306 F.2d 231, 235 (3rd Cir. 1962) (finding petitioner had not provided sufficient evidence that compliance would lead to the "virtual destruction" of a business).