

ORIGINAL

BEFORE THE FEDERAL TRADE COMMISSION

In The Matter of Petitioners
Nordic Clinical, Inc. and Encore Plus Solutions, Inc.

590224

**PETITION BY NORDIC CLINICAL, INC. AND ENCORE PLUS SOLUTIONS, INC.
TO STAY CIVIL INVESTIGATION AND QUASH CIVIL INVESTIGATIVE DEMANDS**

Nordic Clinical, Inc. and Encore Plus Solutions, Inc. (hereinafter, "Petitioners"), pursuant to 16 C.F.R. § 2.10, hereby petition the Federal Trade Commission ("FTC" or "Commission") to stay its civil investigation and quash two Civil Investigative Demands [for] Oral Testimony (the "CIDs") (submitted as Exhibits A&B) dated March 9, 2018 pending the resolution of multiple criminal investigations currently proceeding against Petitioners and their owners and officers.

INTRODUCTORY STATEMENT

Petitioners are marketers of dietary supplement and other health-related products. They have consistently cooperated with the Commission and other regulatory agency and self-regulatory bodies (including NAD) and remain fully prepared to demonstrate the bona fides of their products and business practices.

Here, however, the Commission has propounded the CIDs on a parallel basis with multiple, active trans-national criminal investigations of Petitioners and their owners, Mr. [REDACTED] and Mr. [REDACTED]. The CIDs themselves warn that responses can be shared with other law enforcement agencies. Indeed, one criminal law enforcement agency has already represented under oath that it received and relied on records provided by the FTC. The CIDs go well beyond gathering relevant information sought to assess the veracity of advertising claims and business practices. Rather, by seeking oral testimony during the pendency of criminal investigations, the Commission seeks to jeopardize Petitioners' constitutional and other legal rights.

Unless quashed, the CIDs would violate the Fifth Amendment to the United States Constitution, which forbids the Government from using civil proceedings (including CIDs) to circumvent the strict limits on criminal discovery. Notably, Commission staff has rejected Petitioners' attempts to provide relevant information in a manner that protects their rights.

There are additional problems associated with the CIDs. Petitioners' owners, officers and employees are all citizens and residents of Canada, yet the CIDs purport to compel their attendance at depositions in Florida. Lack of personal jurisdiction, improper venue, forum nonconveniens, and deposition location are additional reasons to quash the CIDs.

BACKGROUND

A. PETITIONERS AND THE CIDs

Nordic Clinical, Inc., LLC is a Delaware entity with its principal place of business in Montreal, Canada. Nordic has no domestic employees and is owned by two nonresident Canadian individuals, Mr. [REDACTED] and Mr. [REDACTED].

Encore Plus Solutions, Inc. is a Florida entity with its principal place of business in Montreal, Canada. Encore has no domestic employees and is owned by Mr. [REDACTED].

In December 2017, the Commission issued two CIDs seeking oral testimony, but on March 9, 2018 withdrew them and reissued the CIDs, which are identical save for the manner of service. The CIDs seek to compel Canadian citizens to travel to Fort Lauderdale, Florida, and provide deposition testimony, including personal information about [REDACTED]. See Exs. A&B, Specifications ##6-9.

B. THE OVERLAPPING CRIMINAL INVESTIGATIONS

Commission staff conceded there are active criminal investigations. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Based on the following facts, it appears that the CIDs were apparently timed and coordinated to advance the ongoing and overlapping criminal investigations:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

³ [REDACTED]

C. THE CIDs SEEK INFORMATION THAT THE GOVERNMENT INTENDS TO SHARE WITH THE OVERLAPPING CRIMINAL INVESTIGATIONS

Any response to the CIDs will certainly be used to advance the criminal investigations. Commission staff has known of Petitioners' position for months now and has steadfastly refused to firewall prior responses away from the Government's criminal investigators, prosecutors and lawyers. The CIDs cover letters warn that the Commission "may disclose the information in response to [...] civil or criminal federal, state, local, or foreign law enforcement agencies for their official law enforcement purposes" as well as "in any federal, state, or foreign civil criminal proceeding[.]"

Notably, the CIDs define "Company" to include Petitioners' individual owners and officers in their individual capacities. *See* Exs. A&B at § D-2 ("Company," "You" or "Your" includes "all directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing"). By obtaining testimony about company owners and sharing it to advance criminal investigations, the Commission would be violating the individuals' Fifth Amendment rights.

D. CONTRADICTING THEIR OWN "SUBJECTS OF INVESTIGATION," THE OVERBROAD CIDs SEEK INFORMATION ABOUT INDIVIDUAL TARGETS

Many of the CIDs' topics bear no relation to the civil investigation, and are obviously designed to glean information for criminal charges against the individual owners. The CIDs' own Subjects of Investigation are self-limited as follows:

Whether Nordic Clinical, Inc., as defined herein, has made false or unsubstantiated representations about the health-related benefits of Neurocet or other products, in violation of Section 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52, and whether Commission action to obtain monetary relief for injury to consumers or others would be in public interest. *See* also attached resolution. [Exhibit A].

Whether Encore Plus Solutions, Inc., as defined herein, has made false or unsubstantiated representations about the health-related benefits of ReGenify, Resetigen-D or other products, in violation of Section 5 and 12 of the FTC Act, 15

U.S.C. §§ 45 and 52, and whether Commission action to obtain monetary relief for injury to consumers or others would be in public interest. See also attached resolution. [Exhibit B].

However, the CIDs also demand information pertaining solely to the individual owners and bearing no relation to any allegedly misrepresented health benefits. *E.g.*:

6. Without regard to time-period, [REDACTED] background, education, training and experience.
7. Without regard to time-period, [REDACTED] background, education, training, and experience.
8. Without regard to time-period, [REDACTED] role in the Company, including his ownership interest in, or duties in connection with, any parent entities, subsidiaries, or affiliated entities.
9. Without regard to time-period, [REDACTED] background, education, training and experience.

Personal information concerning Mr. [REDACTED] and Mr. [REDACTED] is not relevant in any way to challenged claims concerning the health benefits of nutritional supplements. Rather, these topics could be included to advance the criminal investigations. Other topics are similarly directed at persons and entities having nothing to do with the Subjects of Investigation. The inclusion of these questions, as well as the FTC definition of “Company” demonstrate that the Commission’s ability to impermissibly use the CIDs to advance criminal investigations.

E. MEET-AND-CONFER EFFORTS

On January 5, 2018 and counsel conferred about all of the issues raised herein. Petitioners’ counsel offered to accommodate the FTC yet protect the very real Fifth Amendment concerns with two alternate proposals: (a) a tolling agreement (similar to the one reached by the Parties in July 2017) to protect the FTC from being prejudiced by the passage of time yet staying the civil investigation pending the outcome of the criminal investigations; or (b) Petitioners would answer written interrogatories in lieu of depositions subject to the understanding that Petitioners could

assert the Fifth Amendment where appropriate without waiving of any right against self-incrimination. *See* Petitioners' January 8, 2018 letter, submitted as Exhibit H, p.1.

FTC staff rejected both offers to receive information and made no attempt at a solution while at the same time conceding the criminal investigations' existences. Ex. H at p.2 ("we do not know how long any criminal investigations might take and we do not wish to unnecessarily delay moving forward with our own investigation"). Staff otherwise rejected Petitioner's providing the information in a manner that protected Petitioners' right but at the same time provided the requested information. A motion to quash was filed in January, but on March 12, 2018, the CIDs were withdrawn and reissued in virtually identical form. The meet-and-confer process was timely completed after the revised CIDs were issued.

ARGUMENT

In order to ensure that the Fifth Amendment privileges are neither taken, waived nor unduly penalized, this Petition seeks to stay the Commission's civil investigation pending the resolution of all related criminal investigations. At a bare minimum, the CIDs must be quashed to protect these important rights.

A. FIFTH AMENDMENT RIGHTS ARE IMPLICATED BY THE CIDs

There are multiple criminal investigations being conducted and coordinated among various Government agencies. The two CIDs represent an effort to improperly advance the criminal investigations through civil discovery.

The act of compelling deposition testimony implicates Fifth Amendment rights against self-incrimination and covers the compelled production of information that would incriminate the person producing it. *See, e.g., Fisher v. United States*, 425 U.S. 391, 397 (1976). Besides actual testimony, the United States Supreme Court has held that a Government subpoena cannot compel

a holder of information to perform acts that may have testimonial aspects. See *United States v. Doe*, 465 U.S. 605, 612 (1984).

In *United States v. Hubbell*, 530 U.S. 27 (2000), the Supreme Court found that by authenticating or even testifying about documents produced in response to a subpoena, a witness would be admitting that the documents existed, were in his possession or control, and were authentic. *Id.* at 36. *Hubbell* therefore dismissed the indictment and held that the Fifth Amendment protects people who would otherwise be compelled to identify information. *Id.* at 41-42. Of course, the Fifth Amendment also protects from being “compelled to take the witness stand and answer questions designed to determine whether he has produced everything demanded by the subpoena.” *Id.* at 37.

Thus, the Fifth Amendment applies to testimony as well as acts of production and authentication. All are Constitutionally privileged and cannot be compelled without use immunity under 18 U.S.C. §§ 6002-03. *Doe, supra*, at 617.

Under this standard, the CIDs are improper because, in the midst of ongoing criminal investigations, the Government seeks to compel testimony about Petitioner’s owners and executives², as well as to authenticate information and documents. The situation is exacerbated by the Government’s definition of “Company” to include “directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing.”

² The Fifth Amendment protects Canadian citizens. It covers “any person” from being forced to give incriminating testimony. The term “any person” includes foreign nationals questioned outside the United States. *In re Terrorist Bombings of U.S. Embassies in East Africa*, 552 F.3d 177, 201 (2d Cir. 2008). Also, Canadian law, namely section 13 of the Canadian Charter of Rights and Freedoms, gives Petitioners’ owners, officers and employees a right to avoid self-incrimination “in any proceedings.”

Because compelling testimony or authentication of documents breaches the right against self-incrimination, the FTC's investigation should be stayed and the CIDs quashed until the risk of self-incrimination has ended.

**B. THE FIFTH AMENDMENT PROBLEMS CANNOT BE AVOIDED
BY DIRECTING THE CIDs TO CORPORATIONS**

Corporations are empowered to legally assert Constitutional rights in their own capacities, including objections based on the danger of self-incrimination. Older decisions holding that the Fifth Amendment does not apply to corporate entities are of doubtful validity in light of *Citizens United v. FEC*, 558 U.S. 310 (2010) and *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). In *Citizens United*, the Supreme Court rejected the premise that a corporate entity lacked First Amendment rights. *Hobby Lobby* recognized that a closely-held corporation enjoys Constitutional religious liberties under the First Amendment. These authorities require a re-examination of outdated rationales used to deny a corporation's right against self-incrimination.

Although strongly bolstered by these recent precedents, corporations have long been excused from discovery under the Fifth Amendment in cases where no individual can respond on the corporation's behalf without risking self-incrimination. At such times, the appropriate remedy is to postpone civil discovery, including for the corporation. *See State Farm Mut. Auto. Ins. Co. v. Grafman*, No. 04-CV-2609, 2007 WL 4285378, at *3-4 (E.D.N.Y. Dec. 1, 2007) (granting stay to corporations); *Trustees of Plumbers & Pipefitters Nat'l Pension Fund v. Transworld Mechanical, Inc.*, 886 F.Supp. 1134, 1141 (S.D.N.Y. 1995) (granting corporate defendants' motion to stay civil case until criminal case against individual was resolved).

This principle goes beyond single-person entities and applies to closely-held corporations. In *State Farm v. Grafman*, the court excused a corporation controlled by two individuals from responding to interrogatories or producing Rule 30(b)(6) witnesses for deposition when the

corporation represented that no one had sufficient knowledge of the corporation's activities other than the at-risk officers. 2007 WL 4285378 at *3. *See also Volmar Distrib., Inc. v. The New York Post Co., Inc.*, 152 F.R.D. 36, 41 (S.D.N.Y. 1993) (granting complete stay, applicable even to corporations, where individuals asserting Fifth Amendment rights were "central figures" [plural] in the lawsuit).

C. THE APPROPRIATE REMEDY IS A STAY OF ALL CIVIL PROCEEDINGS

In order to assure that Fifth Amendment rights are not compromised, a stay of the FTC's activities is required, particularly because the Government is prosecuting both the civil and criminal proceedings involving the same subject matter.

1. The Differing Scopes of Civil and Criminal Discovery

The scope of civil discovery is broad and requires nearly total mutual disclosure of each party's evidence prior to trial. *Hickman v. Taylor*, 329 U.S. 495, 507 (1947). Civil procedure broadly authorizes discovery of "any matter, not privileged, which is relevant to the subject matter involved in the pending action[.]" Fed.R.Civ.P. 26. The information sought during civil discovery need only be reasonably calculated to lead to discovery of admissible evidence. In civil actions, depositions of all parties plus any other person with relevant testimony are permitted. *Id.*

In contrast, criminal discovery is highly restricted. Fed.R.Crim.P. 15(a) controls the deposition process and permits a party to depose only its own witnesses and then only pursuant to a court order in "exceptional circumstances." Discovery in criminal cases is sharply limited to what is described as discoverable with specificity and detail. *See* Fed.R.Crim.P. 16.

In light of these stark differences, a party should not be forced to choose between invoking the Fifth Amendment in a civil case, thus risking a loss there, or answering the questions thereby risking subsequent criminal prosecution. *See Baxter v. Palmigiano*, 425 U.S. 308, 318-19 (1976).

2. Greater Precautions Are Needed When The Government Is Also A Civil Party

The FTC, as well as federal courts, possesses full discretion to stay civil proceedings, postpone civil discovery and/or impose protective conditions when the interests of justice seem to require such actions. *Matter of Dynamic Health of Florida*, Docket No. 9317, 2004 WL 1814180 (FTC Aug. 2, 2004) (granting stay and citing *United States v. Kordel*, 397 U.S. 1, 12 n.27 (1970)).

Here, the Government's dual role as both civil and criminal investigator is particularly dangerous because it controls both proceedings and is in position to use civil proceedings to improperly advance a criminal investigation. *See, e.g., SEC v. Graystone Nash, Inc.*, 25 F.3d 187, 193-94 (3d Cir. 1994) ("courts must bear in mind that when the government is a party in a civil case and also controls the decision as to whether criminal proceedings will be initiated, special consideration must be given to the plight of the party asserting the Fifth Amendment"); *Sterling National Bank v. A-I Hotels Int's Inc.*, 175 F.Supp.2d 573, 579 (S.D.N.Y. 2001) ("there is a special danger that the government can effectively undermine rights that would exist in a criminal investigation using normally civil means"); *Brock v. Tolchow*, 109 F.R.D. 116, 119 (E.D.N.Y. 1985) (granting pre-indictment stay and because both actions "involve the same subject matter ... and [a stay] is even more appropriate when both actions are brought by the government").

Here, allowing the civil matter to move forward while the criminal investigations are ongoing creates the risk that the Government will use civil discovery to build a criminal case against Petitioners or their owners and officers. *See United States v. Stringer*, 535 F.3d 929 (9th Cir. 2008) (SEC permitted to share information with U.S. Attorney where defendant never invoked Fifth Amendment).

3. There Is Complete Overlap With The Criminal Investigations

The present facts present the strongest case for a stay because the criminal and civil proceedings concern identical conduct, facts and circumstances, namely the marketing of nutritional supplements. *See Brock, supra*, 109 F.R.D. at 119 (granting pre-indictment stay and noting a stay is appropriate “where the civil and criminal actions involve the same matter”); *Chao v. Fleming*, 498 F. Supp.2d 1034, 1039 (W.D. Mich. 2007) (“a stay should issue. The considerations weighing most heavily in the Court's analysis are the almost complete identity of ERISA-related issues in both cases and the fact that the government is the interested party in both cases”); *SEC v. Healthsouth Corp.*, 261 F.Supp.2d 1298, 1326-27 (N.D. Ala. 2003) (granting pre-indictment stay of civil matter because the criminal and civil cases “overlap completely. The issues in both are identical”).

Given the identity of the subject matters of the criminal investigation and civil proceedings, which both concern the same nutritional supplements, it would be impossible to respond to civil deposition questions or answer a complaint without implicating criminal defense strategies or risking self-incrimination. This is an extensive implication of Fifth Amendment concerns, and therefore strongly supports a stay.

4. Pre-Indictment Civil Stays Are Routinely Granted

Due process here dictates that the Petitioners should not be placed in a “Hobson’s Choice” of waiving their Constitutional rights or prejudicing their ability to defend themselves in civil proceedings. If the individuals invoke their Fifth Amendment privilege, Petitioners will have little to offer in their defense and will be irreparably prejudiced in their ability to defend themselves.

A stay of civil litigation is appropriate even though no criminal indictment has been issued. In fact, there are large numbers of decisions in which courts stay civil proceedings prior to an

indictment due to an open criminal investigation. Following is a non-exhaustive list of many such decisions:

- *Wehling v. Columbia Broad. Sys.*, 608 F.2d 1084, 1089 (5th Cir. 1979) (trial court abused its discretion in denying plaintiff's motion for protective order seeking stay of civil proceedings);
- *Kashi v. Gratsos*, 790 F.2d 1050, 1057 (2d Cir. 1986) (pre-indictment stay of civil action was appropriate pending U.S. Attorney's declination to prosecute);
- *United States v. \$557,933.89, More or Less in U.S. Funds*, No. 95-CV-3978 (JG), 1998 WL 817651, at *4 (E.D.N.Y. Mar. 2, 1998) (“I find that the information the government seeks to extract presents a realistic threat of incrimination”);
- *United States v. Certain Real Property and Premises*, 751 F.Supp. 1060, 1063 (E.D.N.Y. 1989) (stay warranted even where claimant was not indicted because Fifth Amendment privilege operates where information sought presents “a realistic threat of incrimination” as distinguished from “mere imaginary possibility”);
- *Brock v. Tolchow*, 109 F.R.D. at 121 (staying discovery in civil case pending outcome of criminal investigation where civil and criminal actions involved same subject matter);
- *Chao v. Fleming*, 498 F.Supp.2d at 1040 (granting stay in part because “an indictment appears to be much more than some fanciful and far-off possibility”);
- *SEC v. Mutuals.com, Inc.*, No. 03-CV-2912-D, 2004 WL 1629929, at *3 (N.D. Tex. July 20, 2004) (staying issued where no indictment existed but preliminary hearing was scheduled);
- *SEC v. Healthsouth Corp.*, 261 F.Supp.2d at 1326 (granting pre-indictment stay where harm to defendant “from blindly pushing ahead with this matter [would] greatly outweigh the prejudice to the SEC from a stay of this civil proceeding”);
- *Baranski v. Fifteen Unknown Agents of ATF*, 195 F.Supp.2d 862, 870 (W.D. Ky. 2002) (“equally salient concerns” are implicated even if plaintiff has not been indicted but is under active criminal investigation);
- *Walsh Secs., Inc. v. Cristo Prop. Mgmt., Ltd.*, 7 F.Supp.2d 523, 527-28 (D.N.J. 1998) (noting several ways in which proceeding with civil

discovery would cause defendants to assert Fifth Amendment privileges, even though those defendants had not yet been indicted);

- *SEC v. Schroeder*, No. C07-03798, 2008 WL 152227, at *2 (N.D. Cal. 2008) (granting motion to delay defendant's deposition because he had shown "the possibility of criminal indictments" and had entered into tolling agreement with Justice Department); and
- *SEC v. Power Securities Corp.*, 142 F.R.D. 321, 323 (D.Col. 1992) (granting defendant's request to postpone his deposition until after time when the grand jury reached a decision as to indictments).

Regardless of whether an indictment has been returned, there is no dispute that there are ongoing coordinated criminal investigations and that FTC information has been or will be shared with such investigators. Requiring a party to provide civil discovery during overlapping investigations threatens to "undermine [the defendant's] Fifth Amendment privilege against self-incrimination, expand rights of criminal discovery beyond the limits of Federal Rule of Criminal Procedure 16(b), expose the basis of the defense to the prosecution in advance of criminal trial, or otherwise prejudice the case." *U.S. v. \$557,933.89, supra*, at *4.

The risk of self-incrimination to the deponents is both real and dangerous, and a stay is equally as appropriate as if an indictment had already been issued.

5. The Stay Applies To Corporations As Well As Individuals

Corporations are covered by the principles set forth above when they cannot mount an adequate defense in light of Fifth Amendment privileges belonging to individual targets.

Corporations can only testify through their officers or employees, and those persons' decision about whether to assert their Fifth Amendment. As one court described:

[C]orporations speak only through their officers and other upper-level managers. Among the senior management of the corporations defending these civil cases are persons who, together with their corporate employers, face criminal charges, and so it may be anticipated that some of these persons will have Fifth Amendment rights to be reckoned with. The dilemma for such persons is severe because they face serious penalties in

the event of a criminal conviction, and because they are not themselves parties to this civil action.

Golden Quality Ice Cream Co. v. Deerfield Specialty Papers, 87 F.R.D. 53, 58 (E.D. Pa. 1980).

Putting aside the issue of corporations' recently expanded Fifth Amendment rights (*see* Section B, *supra*), courts routinely stay civil matters involving corporate defendants when the corporations' ability to defend themselves are threatened by unavailability of witnesses to provide key defensive testimony. *See, e.g., American Express Bus. Fin. Corp. v. R.W. Profl Leasing Servs. Corp.*, 225 F.Supp.2d 263, 265-66 (E.D.N.Y. 2002) (discovery stayed against officers and company); *Bruner Corp v. Balogh*, 819 F.Supp. 811 (E.D. Wis. 1993) (civil proceedings stayed as to corporate defendant as well as the individual, because "it is not likely" that corporation "could proceed to trial without meaningful discovery" from the individual defendants), *rev'd in part on other grounds*, 133 F. 3d 491 (7th Cir. 1998).

American Express involved parallel civil proceedings against individual and entity defendants. The district court stayed civil discovery as to the corporate defendant as well as the individuals, reasoning that the corporate defendant would be unable mount a defense without the availability of the individual defendants, each of whom were executive officers of the defendant corporation. *Id.* at 265-266.

It is settled authority that Fifth Amendment concerns are "more important" than any countervailing effects that might be experienced by the Government. *See SEC v. Healthsouth, supra*, at 1327 (granting stay where "the court finds the harm to defendant Scrusby from blindly pushing ahead with this matter to greatly outweighs the prejudice to the SEC from a stay of this civil proceeding"); *Parker v. Dawson*, No. 06-CV-6191, 2007 WL 2462677, at *1, 5-6 (E.D.N.Y. Aug. 27, 2007) (no indictment but "the interests of justice require a stay of discovery in the civil actions pending resolution of the criminal action"); *Volmar, supra*, 152 F.R.D. at 40 ("this stay

will result in inconvenience and delay to plaintiffs. But under settled authority the Fifth Amendment is the more important consideration”); *Walsh.*, 7 F.Supp.2d at 528 (staying depositions and other discovery because a court has discretion to grant a in the interests of justice); *Brock v. Tolkow*, 109 F.R.D. at 121 (“all discovery in this action is hereby stayed pending the outcome of the current investigation of the Organized Crime and Racketeering Section”).

D. JURISDICTION, VENUE AND RELATED ISSUES

All objections with respect to personal jurisdiction, service of process, venue, forum nonconveniens, deposition location, etc., are hereby reserved and asserted as additional reasons to quash the CIDs.

Petitioners have no executives, officers or agents located in the United States. Foreigners located outside the United States are beyond the subpoena power of our courts. *See* 28 U.S.C.A. § 1783(a). If a foreign witness refuses to appear voluntarily, the U.S. litigant's recourse is to serve process “in accordance with the provisions of the Federal Rules of Civil Procedure relating to service of process on a person in a foreign country.” *See* 28 U.S.C.A. § 1783(b). That has not even been attempted here.

Second, the Government is unable to compel the attendance of individuals who are neither U.S. citizens, U.S. residents nor located in this country. *See Triumph Aerostructures, LLC v. Comau, Inc.*, No. 14-CV-2329, 2015 WL 5502625, at *16 (N.D. Tex. Sept. 18, 2015) (domestic subpoena insufficient to compel deposition absent a request for international judicial assistance); *Walton v. Bilinski*, No. 15-CV-36 CDP, 2015 WL 9489610 (E.D. Mo. Dec. 30, 2015) (requiring service upon Canadian individual to be perfected in accordance with Fed.R.Civ.P. 4(f)).

Even if personal jurisdiction over the individuals is established and proper procedures completed by the Commission, that is insufficient to compel a Canadian individual to appear in

Florida. The usual rule in federal litigation is that a party seeking discovery must go where the witnesses are located. *Yaskawa Elec. Corp. v. Kollmorgen Corp.*, 201 F.R.D. 443, 444 (N.D. Ill. 2001). All rights are reserved with respect to the locale of any deposition.

Courts routinely require that depositions of corporate employees take place in their home countries. *E.g.*, *Yaskawa*, 201 F.R.D. at 444-45 (plaintiff's employees could not be compelled to travel from Japan to Chicago); *Motion Games, LLC v. Nintendo Co., Ltd.*, No. 12-cv-878, 2014 WL 5306961 (E.D. Tex. 2014) (Nintendo employees should be deposed in Japan); *Boss Mfg. Co. v. Hugo Boss AG*, No. 97 CIV 8495, 1999 WL 20828, at *2 (S.D.N.Y. Jan. 13, 1999) (defendant's CFO must be deposed in Germany).

CONCLUSION

For all of the foregoing reasons, the FTC's civil investigation should be stayed and the CIDs quashed pending the resolution of the related criminal investigations.

Dated: March 30, 2018

OLSHAN FROME WOLOSKY LLP

By: /s/ Andrew B. Lustigman

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*Attorneys for Petitioners Nordic Clinical,
Inc. and Encore Plus Solutions, Inc.*

CERTIFICATION

Pursuant to 16 C.F.R. §§ 2.7(k) and 2.10(a)(2), counsel for Petitioners hereby certifies that on January 5, 2018, the undersigned met and conferred with Federal Trade Commission counsel by telephone in a good-faith attempt to resolve the issues set forth in this Petition, but the attorneys were unable to reach agreement. Subsequent efforts, including written correspondence, were made in good faith during the month of March 2018 and the attorneys remained unable to reach an agreement.

Dated: March 30, 2018

/s/ Andrew B. Lustigman

Andrew B. Lustigman

*Attorneys for Petitioners Nordic Clinical, Inc.
and Encore Plus Solutions, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on or before March 30, 2018, on behalf of Petitioners Nordic Clinical, Inc. and Encore Plus Solutions, Inc., I caused the original and twelve copies of the foregoing Petition, with attached exhibits, to be filed with the Secretary of the Federal Trade Commission by overnight courier delivery to 600 Pennsylvania Avenue, NW, Washington, DC 20580.

I further certify that I caused an additional copy to be served by overnight courier delivery to the following Federal Trade Commission Counsel named in section 8 of the Civil Investigative Demands:

Edward Glennon and Mamie Kresses, Federal Trade Commission, 600 Pennsylvania Ave., NW, Mailstop CC-10532, Washington, DC 20580.

/s/ Anna Bivona

Anna Bivona

EXHIBIT A



Office of the Secretary

United States of America
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

March 9, 2018

Via Federal Express

Nordic Clinical, Inc.
c/o Registered Agent



Re: FTC Matter No. 1723143

Dear Sir or Madam:

The Federal Trade Commission ("FTC" or "Commission") has issued the attached Civil Investigative Demand ("CID") for the oral testimony of Nordic Clinical, Inc., by its officers, directors, managing agents, or others qualified to testify on its behalf. This replacement CID is identical to the CID issued to Nordic Clinical, Inc. by the Commission on December 19, 2017, with the exception that the enclosed CID is addressed to the company in care of its Registered Agent. Copies of this letter and the attached CID also have been sent to the corporate address and to counsel of record, Andrew B. Lustigman, Esq.

The Commission has issued the attached CID asking for the company's oral testimony as part of a non-public investigation. Our purpose is to determine whether Nordic Clinical, Inc., as defined herein, has made false or unsubstantiated representations about the health-related benefits of Neurocet or other products, in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52, and whether Commission action to obtain monetary relief for injury to consumers or others would be in the public interest. Please read the attached documents carefully. Here are a few important points we would like to highlight:

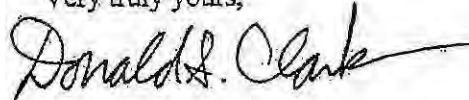
1. **Contact FTC counsel, Mamie Kresses, at (202) 326-2070 or mkresses@ftc.gov, or Edward Glennon, at (202) 326-3126 or eglennon@ftc.gov, as soon as possible to schedule an initial meeting to be held within 14 days. You can meet in person or by phone to discuss any questions you have, including whether there are changes to how you comply with the CID that would reduce your cost or burden while still giving the FTC the information it needs. Please read the attached documents for more information about that meeting.**
2. **You must immediately stop any routine procedures for electronic or paper document destruction, and you must preserve all paper or electronic documents that are in any way relevant to this investigation, even if you believe the documents are protected from discovery by privilege or some other reason.**

REDACTED PUBLIC VERSION

3. **The FTC will use the testimony and information you provide in response to the CID for the purpose of investigating violations of the laws the FTC enforces.** We will not disclose the information under the Freedom of Information Act, 5 U.S.C. § 552. We may disclose the information in response to a valid request from Congress, or other civil or criminal federal, state, local, or foreign law enforcement agencies for their official law enforcement purposes. The FTC or other agencies may use and disclose your response in any federal, state, or foreign civil or criminal proceeding, or if required to do so by law. However, we will not publicly disclose your information without giving you prior notice.
4. **Please read the attached documents closely.** They contain important information about when and where the company's designee(s) must appear.

Please contact FTC counsel as soon as possible to set up an initial meeting. We appreciate your cooperation.

Very truly yours,



Donald S. Clark
Secretary of the Commission



CIVIL INVESTIGATIVE DEMAND
Oral Testimony

<p>1. TO</p> <p>Nordic Clinical, Inc. c/o Registered Agent</p> <p>[REDACTED]</p>	<p>2. FROM</p> <p align="center">UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION</p> <hr/> <p>2a. MATTER NUMBER 1723143</p>
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This demand is issued pursuant to Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, in the course of an investigation to determine whether there is, has been, or may be a violation of any laws administered by the Federal Trade Commission by conduct, activities or proposed action as described in Item 6.

<p>3. LOCATION OF HEARING</p> <p>Office of the U.S. Attorney 500 East Broward Boulevard Ft. Lauderdale, FL 33304</p>	<p>4. YOUR APPEARANCE WILL BE BEFORE</p> <p>Edward Glennon, Mamie Kresses, or other duly designated person</p> <hr/> <p>5. DATE AND TIME OF HEARING</p> <p>April 26, 2018; 9:00 AM</p>
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6. SUBJECT OF INVESTIGATION

See attached Schedule and attached resolution.

<p>7. RECORDS CUSTODIAN/DEPUTY CUSTODIAN</p> <p>Lynne Colbert/Edward Glennon Federal Trade Commission 600 Pennsylvania Avenue, NW, Mailstop CC-10532 Washington, DC 20580</p>	<p>8. COMMISSION COUNSEL</p> <p>Edward Glennon and Mamie Kresses Federal Trade Commission 600 Pennsylvania Avenue, NW, Mailstop CC-10532 Washington, DC 20580</p>
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<p>DATE ISSUED</p> <p align="center">3/9/18</p>	<p>COMMISSIONER'S SIGNATURE</p> <p align="center"><i>Edward Glennon</i></p>
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INSTRUCTIONS AND NOTICES

The delivery of this demand to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply. This demand does not require approval by OMB under the Paperwork Reduction Act of 1980.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this demand be filed within 20 days after service, or, if the return date is less than 20 days after service, prior to the return date. The original and twelve copies of the petition must be filed with the Secretary of the Federal Trade Commission, and one copy should be sent to the Commission Counsel named in Item 8.

YOUR RIGHTS TO REGULATORY ENFORCEMENT FAIRNESS

The FTC has a longstanding commitment to a fair regulatory enforcement environment. If you are a small business (under Small Business Administration standards), you have a right to contact the Small Business Administration's National Ombudsman at 1-888-REGFAIR (1-888-734-3247) or www.sba.gov/ombudsman regarding the fairness of the compliance and enforcement activities of the agency. You should understand, however, that the National Ombudsman cannot change, stop, or delay a federal agency enforcement action.

The FTC strictly forbids retaliatory acts by its employees, and you will not be penalized for expressing a concern about these activities.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this demand should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this demand and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

A copy of the Commission's Rules of Practice is available online at <http://bit.ly/FTCRulesofPractice>. Paper copies are available upon request.

Form of Certificate of Compliance*

I/We do certify that all of the information required by the attached Civil Investigative Demand which is in the possession, custody, control, or knowledge of the person to whom the demand is directed has been submitted to a custodian named herein.

If an interrogatory or a portion of the request has not been fully answered or portion of the report has not been completed the objection to such interrogatory or uncompleted portion and the reasons for the objection have been stated.

Signature _____

Title _____

Sworn to before me this day

Notary Public

*In the event that more than one person is responsible for answering the interrogatories or preparing the report, the certificate shall identify the interrogatories or portion of the report for which each certifying individual was responsible. In place of a sworn statement, the above certificate of compliance may be supported by an unsworn declaration as provided for by 28 U.S.C. § 1746.

**CIVIL INVESTIGATIVE DEMAND
TO NORDIC CLINICAL, INC.
SCHEDULE FOR ORAL TESTIMONY
FTC File No. 1723143**

Meet and Confer: You must contact FTC counsel, Mamie Kresses, at mkresses@ftc.gov or (202) 326-2076, or Edward Glennon, at eglennon@ftc.gov or (202)326-3126, as soon as possible to schedule a meeting (telephonic or in person) to be held within fourteen (14) days after you receive this CID. At the meeting, you must discuss with FTC counsel any questions you have regarding this CID or any possible CID modifications that could reduce your cost, burden, or response time yet still provide the FTC with the information it needs to pursue its investigation.

Document Retention: You must retain all documentary materials used in preparing responses to this CID. The FTC may require the submission of additional documents later during this investigation. Accordingly, you must suspend any routine procedures for document destruction and take other measures to prevent the destruction of documents that are in any way relevant to this investigation, even if you believe those documents are protected from discovery. See 15 U.S.C. § 50; see also 18 U.S.C. §§ 1505, 1519.

Sharing of Information: The FTC will use information you provide in response to the CID for purposes of investigating violations of the laws the FTC enforces. We will not disclose such information under the Freedom of Information Act, 5 U.S.C. § 552. We also will not disclose such information, except as allowed under the FTC Act (15 U.S.C. § 57b-2), the Commission's Rules of Practice (16 C.F.R. §§ 4.10 & 4.11), or if required by a legal obligation. Under the FTC Act, we may provide your information in response to a request from Congress or a proper request from another law enforcement agency. However, we will not publicly disclose such information without giving you prior notice.

Definitions and Instructions: Please review carefully the Definitions and Instructions that appear after the Specifications and provide important information regarding compliance with this CID.

SUBJECT OF INVESTIGATION











Whether Nordic Clinical, Inc., as defined herein, has made false or unsubstantiated representations about the health-related benefits of Neurocet or other products, in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52, and whether Commission action to obtain monetary relief for injury to consumers or others would be in the public interest. See also attached resolution.

SPECIFICATIONS

Applicable time-period: Unless otherwise directed in the specifications, the applicable time period for the request shall be from January 1, 2015 until the date of full and complete compliance with this CID.

A. **Investigational Hearing Testimony:** The Company must designate and make available one or more officers, directors, or managing agents, or others who consent, to testify on its behalf. Unless a single individual is designated, the Company must designate in advance and in writing the matters on which each designee will testify. The person(s) designated must testify about information known or reasonably available to the Company, and their testimony shall be binding upon it, 16 C.F.R. §2.7(h). The persons designated must be prepared to provide testimony relating to the following topics:

1. Responses by the Company to the Federal Trade Commission's Civil Investigative Demand issued on June 15, 2017, and modified in part by Associate Director Mary K. Engle by letter dated August 24, 2017.
2. The content, subject, history, and context of documents produced by the Company in response to the Federal Trade Commission's Civil Investigative Demand issued on June 15, 2017, and modified in part by Associate Director Mary K. Engle by letter dated August 24, 2017.
3. Without regard to time period, the history, structure, organization, and business of the Company, including the duties and responsibilities of its officers, directors, managers, employees, agents, and contractors.
4. The Company's sales, revenues, cash flow, compensation of officers, shareholders, and employees, and allocations of equity or debt between any related entities.
5. The Company's advertising costs, costs of goods sold, debts, or loans granted or received.
6. Without regard to time-period, [REDACTED] role in the Company, including his ownership interest in, or duties in connection with, any parent entities, subsidiaries, or affiliated entities.
7. Without regard to time-period, [REDACTED] background, education, training, and experience.
8. Without regard to time-period, [REDACTED] role in the Company, including his ownership interest in, or duties in connection with, any parent entities, subsidiaries, or affiliated entities.
9. Without regard to time-period, [REDACTED] background, education, training, and experience.
10. Without regard to time-period, the formulation and development of Neurocet or any substantially similar product, and the persons, entities, and timelines involved.
11. Without regard to time-period, the manufacturing and labeling of Neurocet or any substantially similar product, and the persons, entities, and timelines involved.

12. Without regard to time-period, research, testing, and substantiation relating to Neurocet or any substantially similar products, constituent ingredients, or product claims, and the persons, entities, and timelines involved.
13. Without regard to time-period, advertising or marketing of Neurocet or any substantially similar product, including development of product claims, and the persons, entities, and timelines involved.
14. Complaints from any source regarding Neurocet or any substantially similar product.
15. Company policies and practices regarding complaints, testimonials, endorsements, refunds, chargebacks, and returns.
16. Without regard to time-period, the relationship between the Company and each of the following:
 - a. 
 - b. 
 - c. 
 - d. 
17. Without regard to time period, the Company's involvement, communications, or interactions with each of the following persons or companies:
 - a. 
 - b. 
 - c. 
 - d. 
 - e. 
 - f. 
18. Company policy and practice regarding retention of documents or records.

DEFINITIONS

The following definitions apply to this CID:

D-1. "Advertisement" or "Advertising" or "Ad" means any written or verbal statement, illustration, or depiction that promotes the sale or use of a good or service or is designed to increase consumer interest in a brand, good, or service. Advertising media includes, but is not limited to: packaging and labeling; promotional materials; print; television; radio; and Internet, social media, and other digital content.

D-2. "Company," "You," or "Your" means Nordic Clinical, Inc., its wholly or partially owned subsidiaries, unincorporated divisions, joint ventures, operations under assumed names, and affiliates, and all directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing.

D-3. "Document" means the complete original, all drafts, and any non-identical copy, whether different from the original because of notations on the copy, different metadata, or otherwise, of any item covered by 15 U.S.C. § 57b-1(a)(5), 16 C.F.R. § 2.7(a)(2), or Federal Rule of Civil Procedure 34(a)(1)(A).

INSTRUCTIONS

I-1. **Petitions to Limit or Quash:** You must file any petition to limit or quash this CID with the Secretary of the FTC no later than twenty (20) days after service of the CID, or, if the return date is less than twenty (20) days after service, prior to the return date. Such petition must set forth all assertions of protected status or other factual and legal objections to the CID and comply with the requirements set forth in 16 C.F.R. § 2.10(a)(1) – (2). The FTC will not consider petitions to quash or limit if you have not previously met and conferred with FTC staff and, absent extraordinary circumstances, will consider only issues raised during the meet and confer process. 16 C.F.R. § 2.7(k); *see also* § 2.11(b). If you file a petition to limit or quash, you must still timely respond to all requests that you do not seek to modify or set aside in your petition. 15 U.S.C. § 57b-1(f); 16 C.F.R. § 2.10(b).

I-2. **Modification of Specifications:** The Bureau Director, a Deputy Bureau Director, Associate Director, Regional Director, or Assistant Regional Director must agree in writing to any modifications of this CID. 16 C.F.R. § 2.7(l).

I-3. **Oral Testimony Procedures:** The taking of oral testimony pursuant to this CID will be conducted in conformity with Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, and with Part 2A of the FTC's Rules, 16 C.F.R. §§2.7(f), 2.7(h), and 2.9.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

RESOLUTION DIRECTING USE OF COMPULSORY PROCESS IN A NONPUBLIC
INVESTIGATION OF UNNAMED PERSONS ENGAGED DIRECTLY OR
INDIRECTLY IN THE ADVERTISING OR MARKETING OF DIETARY
SUPPLEMENTS, FOODS, DRUGS, DEVICES, OR ANY OTHER PRODUCT OR
SERVICE INTENDED TO PROVIDE A HEALTH BENEFIT OR TO AFFECT THE
STRUCTURE OR FUNCTION OF THE BODY

File No. 0023191

Nature and Scope of Investigation:

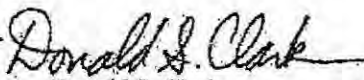
To investigate whether unnamed persons, partnerships, or corporations, or others engaged directly or indirectly in the advertising or marketing of dietary supplements, foods, drugs, devices, or any other product or service intended to provide a health benefit or to affect the structure or function of the body have misrepresented or are misrepresenting the safety or efficacy of such products or services, and therefore have engaged or are engaging in unfair or deceptive acts or practices or in the making of false advertisements, in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52. The investigation is also to determine whether Commission action to obtain redress for injury to consumers or others would be in the public interest.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation for a period not to exceed ten (10) years from the date of issuance of this resolution. The expiration of this ten (10) year period shall not limit or terminate the investigation or the legal effect of any compulsory process issued during the ten (10) year period. The Federal Trade Commission specifically authorizes the filing or confirmation of actions to enforce any such compulsory process after expiration of the ten-year period.

Authority to conduct investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. § 1.1 et seq., and supplements thereto.

By direction of the Commission.



Donald S. Clark
Secretary

Issued: August 13, 2009

EXHIBIT B



Office of the Secretary

United States of America
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

March 9, 2018

Via Federal Express

Encore Plus Solutions, Inc.
c/o Registered Agent



Re: FTC Matter No. 1723132

Dear Sir or Madam:

The Federal Trade Commission ("FTC" or "Commission") has issued the attached Civil Investigative Demand ("CID") for the oral testimony of Encore Plus Solutions, Inc., by its officers, directors, managing agents, or others qualified to testify on its behalf. This replacement CID is identical to the CID issued to Encore Plus Solutions, Inc. by the Commission on December 19, 2017, with the exception that the enclosed CID is addressed to the company in care of its Registered Agent. Copies of this letter and the attached CID also have been sent to the corporate address and to counsel of record, Andrew B. Lustigman, Esq.

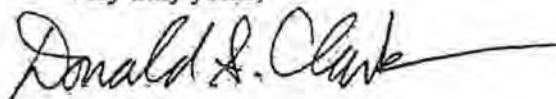
The Commission has issued the attached CID asking for the company's oral testimony as part of a non-public investigation. Our purpose is to determine whether Encore Plus Solutions, Inc., as defined herein, has made false or unsubstantiated representations about the health-related benefits of ReGenify, Resetigen-D, or other products, in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52, and whether Commission action to obtain monetary relief for injury to consumers or others would be in the public interest. Please read the attached documents carefully. Here are a few important points we would like to highlight:

1. **Contact FTC counsel, Mamie Kresses, at (202) 326-2070 or mkresses@ftc.gov, or Edward Glennon, at (202) 326-3126 or eglennon@ftc.gov, as soon as possible to schedule an initial meeting to be held within 14 days. You can meet in person or by phone to discuss any questions you have, including whether there are changes to how you comply with the CID that would reduce your cost or burden while still giving the FTC the information it needs. Please read the attached documents for more information about that meeting.**
2. **You must immediately stop any routine procedures for electronic or paper document destruction, and you must preserve all paper or electronic documents that are in any way relevant to this investigation, even if you believe the documents are protected from discovery by privilege or some other reason.**

3. The FTC will use the testimony and information you provide in response to the CID for the purpose of investigating violations of the laws the FTC enforces. We will not disclose the information under the Freedom of Information Act, 5 U.S.C. § 552. We may disclose the information in response to a valid request from Congress, or other civil or criminal federal, state, local, or foreign law enforcement agencies for their official law enforcement purposes. The FTC or other agencies may use and disclose your response in any federal, state, or foreign civil or criminal proceeding, or if required to do so by law. However, we will not publicly disclose your information without giving you prior notice.
4. Please read the attached documents closely. They contain important information about when and where the company's designee(s) must appear.

Please contact FTC counsel as soon as possible to set up an initial meeting. We appreciate your cooperation.


Very truly yours,



Donald S. Clark
Secretary of the Commission



CIVIL INVESTIGATIVE DEMAND
Oral Testimony

1. TO Encore Plus Solutions, Inc. c/o Registered Agent 	2. FROM UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION 2a. MATTER NUMBER 1723132
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This demand is issued pursuant to Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, in the course of an investigation to determine whether there is, has been, or may be a violation of any laws administered by the Federal Trade Commission by conduct, activities or proposed action as described in Item 6.

3. LOCATION OF HEARING Office of the U.S. Attorney 500 East Broward Boulevard Ft. Lauderdale, FL 33394	4. YOUR APPEARANCE WILL BE BEFORE Mamie Kresses, Edward Glennon, or other duly designated person 5. DATE AND TIME OF HEARING April 25, 2018; 9:00 AM
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6. SUBJECT OF INVESTIGATION

See attached Schedule and attached resolution.

7. RECORDS CUSTODIAN/DEPUTY CUSTODIAN Lynne Colbert/Mamie Kresses Federal Trade Commission 600 Pennsylvania Avenue, NW, Mailstop CC-10532 Washington, DC 20580	8. COMMISSION COUNSEL Mamie Kresses and Edward Glennon Federal Trade Commission 600 Pennsylvania Avenue, NW, Mailstop CC-10532 Washington, DC 20580
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DATE ISSUED 3/9/18	COMMISSIONER'S SIGNATURE 
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INSTRUCTIONS AND NOTICES

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A copy of the Commission's Rules of Practice is available online at <http://bit.ly/FTCRulesofPractice>. Paper copies are available upon request.

Form of Certificate of Compliance*

I/We do certify that all of the information required by the attached Civil Investigative Demand which is in the possession, custody, control, or knowledge of the person to whom the demand is directed has been submitted to a custodian named herein.

If an interrogatory or a portion of the request has not been fully answered or portion of the report has not been completed the objection to such interrogatory or uncompleted portion and the reasons for the objection have been stated.

Signature _____

Title _____

Sworn to before me this day

Notary Public

*In the event that more than one person is responsible for answering the interrogatories or preparing the report, the certificate shall identify the interrogatories or portion of the report for which each certifying individual was responsible. In place of a sworn statement, the above certificate of compliance may be supported by an unsworn declaration as provided for by 28 U.S.C. § 1746.

**CIVIL INVESTIGATIVE DEMAND
TO ENCORE PLUS SOLUTIONS, INC.
SCHEDULE FOR ORAL TESTIMONY
FTC File No. 1723132**

Meet and Confer: You must contact FTC counsel, Mamie Kresses, at mkresses@ftc.gov or (202) 326-2070, or Edward Glennon, at eglennon@ftc.gov or (202) 326-3126, as soon as possible to schedule a meeting (telephonic or in person) to be held within fourteen (14) days after you receive this CID. At the meeting, you must discuss with FTC counsel any questions you have regarding this CID or any possible CID modifications that could reduce your cost, burden, or response time yet still provide the FTC with the information it needs to pursue its investigation.

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Sharing of Information: The FTC will use information you provide in response to the CID for purposes of investigating violations of the laws the FTC enforces. We will not disclose such information under the Freedom of Information Act, 5 U.S.C. § 552. We also will not disclose such information, except as allowed under the FTC Act (15 U.S.C. § 57b-2), the Commission's Rules of Practice (16 C.F.R. §§ 4.10 & 4.11), or if required by a legal obligation. Under the FTC Act, we may provide your information in response to a request from Congress or a proper request from another law enforcement agency. However, we will not publicly disclose such information without giving you prior notice.

Definitions and Instructions: Please review carefully the Definitions and Instructions that appear after the Specifications and provide important information regarding compliance with this CID.

SUBJECT OF INVESTIGATION











Whether Encore Plus Solutions, Inc., as defined herein, has made false or unsubstantiated representations about the health-related benefits of ReGenify, Resetigen-D, or other products, in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52, and whether Commission action to obtain monetary relief for injury to consumers or others would be in the public interest. See also attached resolution.

SPECIFICATIONS

Applicable time-period: Unless otherwise directed in the specifications, the applicable time-period for the request shall be from January 1, 2015 until the date of full and complete compliance with this CID.

A. **Investigational Hearing Testimony:** The Company must designate and make available one or more officers, directors, or managing agents, or others who consent, to testify on its behalf. Unless a single individual is designated, the Company must designate in advance and in writing the matters on which each designee will testify. The person(s) designated must testify about information known or reasonably available to the Company, and their testimony shall be binding upon it. 16 C.F.R. §2.7(h). The persons designated must be prepared to provide testimony relating to the following topics:

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3. Without regard to time period, the history, structure, organization, and business of the Company, including the duties and responsibilities of its officers, directors, managers, employees, agents, and contractors.
4. The Company's sales, revenues, cash flow, compensation of officers, shareholders, and employees, and allocations of equity or debt between any related entities.
5. The Company's advertising costs, costs of goods sold, debts, or loans granted or received.
6. Without regard to time-period, [REDACTED] role in the Company, including his ownership interest in, or duties in connection with, any parent entities, subsidiaries, or affiliated entities.
7. Without regard to time-period, [REDACTED] background, education, training, and experience.
8. Without regard to time-period, [REDACTED] role in the Company, including his ownership interest in, or duties in connection with, any parent entities, subsidiaries, or affiliated entities.
9. Without regard to time-period, [REDACTED] background, education, training, and experience.
10. Without regard to time-period, the formulation and development of Regenify, Restigen-D, or any substantially similar product, and the persons, entities, and timelines involved.
11. Without regard to time-period, the manufacturing and labeling of Regenify, Restigen-D, or any substantially similar product, and the persons, entities, and timelines involved.

12. Without regard to time-period, research, testing, and substantiation relating to Regenify, Restigen-D, or any substantially similar products, constituent ingredients, or product claims, and the persons, entities, and timelines involved.
13. Without regard to time-period, advertising or marketing of Regenify, Resetigen-D, or any substantially similar product, including development of product claims, and the persons, entities, and timelines involved.
14. Complaints from any source regarding Regenify, Resetigen-D, or any substantially similar product.
15. Company policies and practices regarding complaints, testimonials, endorsements, refunds, chargebacks, and returns.
16. Without regard to time-period, the relationship between the Company and each of the following:
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 - b. 
 - c. 
 - d. 
17. Without regard to time period, the Company's involvement, communications, or interactions with each of the following persons or companies:
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 - d. 
 - e. 
 - f. 
18. Company policy and practice regarding retention of documents or records.

DEFINITIONS

The following definitions apply to this CID:

D-1. "Advertisement" or "Advertising" or "Ad" means any written or verbal statement, illustration, or depiction that promotes the sale or use of a good or service or is designed to increase consumer interest in a brand, good, or service. Advertising media includes, but is not limited to: packaging and labeling; promotional materials; print; television; radio; and Internet, social media, and other digital content.

D-2. "Company," "You," or "Your" means Encore Plus Solutions, Inc., its wholly or partially owned subsidiaries, unincorporated divisions, joint ventures, operations under assumed names, and affiliates, and all directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing.

D-3. "Document" means the complete original, all drafts, and any non-identical copy, whether different from the original because of notations on the copy, different metadata, or otherwise, of any item covered by 15 U.S.C. § 57b-1(a)(5), 16 C.F.R. § 2.7(a)(2), or Federal Rule of Civil Procedure 34(a)(1)(A).

INSTRUCTIONS

I-1. **Petitions to Limit or Quash:** You must file any petition to limit or quash this CID with the Secretary of the FTC no later than twenty (20) days after service of the CID, or, if the return date is less than twenty (20) days after service, prior to the return date. Such petition must set forth all assertions of protected status or other factual and legal objections to the CID and comply with the requirements set forth in 16 C.F.R. § 2.10(a)(1)–(2). The FTC will not consider petitions to quash or limit if you have not previously met and conferred with FTC staff and, absent extraordinary circumstances, will consider only issues raised during the meet and confer process. 16 C.F.R. § 2.7(k); *see also* § 2.11(b). If you file a petition to limit or quash, you must still timely respond to all requests that you do not seek to modify or set aside in your petition. 15 U.S.C. § 57b-1(f); 16 C.F.R. § 2.10(b).

I-2. **Modification of Specifications:** The Bureau Director, a Deputy Bureau Director, Associate Director, Regional Director, or Assistant Regional Director must agree in writing to any modifications of this CID. 16 C.F.R. § 2.7(l).

I-3. **Oral Testimony Procedures:** The taking of oral testimony pursuant to this CID will be conducted in conformity with Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, and with Part 2A of the FTC's Rules, 16 C.F.R. §§ 2.7(f), 2.7(h), and 2.9.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

RESOLUTION DIRECTING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION OF UNNAMED PERSONS ENGAGED DIRECTLY OR INDIRECTLY IN THE ADVERTISING OR MARKETING OF DIETARY SUPPLEMENTS, FOODS, DRUGS, DEVICES, OR ANY OTHER PRODUCT OR SERVICE INTENDED TO PROVIDE A HEALTH BENEFIT OR TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY

File No. 0023191

Nature and Scope of Investigation:

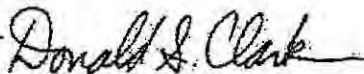
To investigate whether unnamed persons, partnerships, or corporations, or others engaged directly or indirectly in the advertising or marketing of dietary supplements, foods, drugs, devices, or any other product or service intended to provide a health benefit or to affect the structure or function of the body have misrepresented or are misrepresenting the safety or efficacy of such products or services, and therefore have engaged or are engaging in unfair or deceptive acts or practices or in the making of false advertisements, in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52. The investigation is also to determine whether Commission action to obtain redress for injury to consumers or others would be in the public interest.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation for a period not to exceed ten (10) years from the date of issuance of this resolution. The expiration of this ten (10) year period shall not limit or terminate the investigation or the legal effect of any compulsory process issued during the ten (10) year period. The Federal Trade Commission specifically authorizes the filing or continuation of actions to enforce any such compulsory process after expiration of the ten year period.

Authority to conduct investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. § 1.1 et seq. and supplements thereto.

By direction of the Commission.



Donald S. Clark
Secretary

Issued: August 13, 2009

EXHIBIT C

REDACTED

REDACTED PUBLIC VERSION

EXHIBIT D

REDACTED PUBLIC VERSION

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

In re the Matter of the Search of the Premises
of Specialty Fulfillment Center (DBA AC
Fillers), 3 17th St. S., Nampa, ID

Case No. 1:17-mj-9885-CWD

**GOVERNMENT'S RESPONSE TO
NORDIC CLINICAL'S MOTION FOR
RETURN OF PROPERTY PURSUANT
TO FEDERAL RULE OF CRIMINAL
PROCEDURE 41(g)**

The United States of America, by and through Bart M. Davis, United States Attorney, and the undersigned Assistant United States Attorney for the District of Idaho, hereby asks the Court to deny Nordic Clinical's Motion for Return of Property Pursuant to Federal Rule of Criminal Procedure 41(g).

INTRODUCTION

In this action under Rule 41(g) of the Federal Rules of Criminal Procedure, the movant, Nordic Clinical, Inc. (hereafter, "Nordic") asks this court to return various drug products seized from Specialty Fulfillment Center (DBA AC Fillers), 3 17th St. S., Nampa, ID, during the execution of a lawful search warrant on September 26, 2017, claiming both that the seizure was improper, and that the drugs at issue are otherwise lawfully marketed products. Because both

claims of Nordic are incorrect, the motion should be denied.

The Court should not provide the relief requested by Nordic for two reasons: first, because Nordic does not set forth facts that would support the Court's exercise of equitable jurisdiction, and second, because the unapproved new drugs and misbranded drugs that are contraband as well as evidence and instrumentalities in an ongoing criminal investigation cannot be returned. Likewise, under the equitable doctrine of Unclean Hands, the court should not return unmerchantable goods that were illegally introduced into interstate commerce.

FACTUAL BACKGROUND

On September 26, 2017, government agents executed a criminal search warrant at the premises of Specialty Fulfillment Center (DBA AC Fillers), 3 17th St. S., Nampa, ID. The search warrant affidavit, which was filed under seal, established probable cause to believe that evidence, instrumentalities, and records relating to violations of 21 U.S.C § 331 of the federal Food, Drug, and Cosmetic Act (FDCA) would be found at the premises. The warrant, issued by this Court, authorized the executing agents to seize, among other things:



b. All records and information

Exhibit A, ECF No. 4-3, p. 6-10.

During the execution of the warrant, law enforcement officers seized, among

other things, approximately 3500 bottles of various products labeled as “dietary supplements” and approximately 2800 packages of products labeled as “Actaflex” pain creams. *Id.* at p. 4-6. It is these products, labeling for various Nordic products, and two folders labeled “Nordic” that are the subject of Nordic’s Motion. ECF No. 4-1, p. 2-3.

ARGUMENT

In this case, not only do the balance of equities weigh in favor of the Government, but the nature of the products—unapproved new drugs and misbranded drugs shipped in interstate commerce—would bar their return altogether.

The movant does not set forth facts sufficient for the Court to exercise its equitable jurisdiction and reach the merits of the motion. Under Federal Rule of Criminal Procedure 41(g), “A person aggrieved by an unlawful search and seizure of property or by the deprivation of property may move for the property’s return.” When there are no criminal proceedings pending against the movant, Rule 41(g) motions are treated as civil proceedings invoking the court's equitable powers. *Ramsden v. U.S.*, 2 F.3d 322, 324 (9th Cir. 1993).¹ The *Ramsden* court articulated four factors a court should consider in determining whether to entertain a Rule 41(g) motion made prior to initiation of criminal proceedings:

- (1) whether the Government displayed a callous disregard for the constitutional rights of the movant;
- (2) whether the movant has an individual interest in and need for the property he wants returned;
- (3) whether the movant would be irreparably injured by denying return of the property; and
- (4) whether the movant has an adequate remedy at law for the redress of his grievance.

Id. at 325. No single factor is determinative. “If the ‘balance of equities tilts in favor of reaching

¹ At the time *Ramsden* was decided, Rule 41(e) governed return of property seized during a search warrant. *Ramsden*, 2 F.3d 322, n. 1.

the merits' of the Rule 41(g) motion, the district court should exercise its equitable jurisdiction to entertain the motion. *United States v. Kama*, 394 F.3d 1236, 1238 (9th Cir. 2005) (quoting *Ramsden*, 2 F.3d at 326.).

However, even if a court might otherwise entertain a motion under Rule 41(g), the motion must be denied "if the defendant is not entitled to lawful possession of the seized property, the property is contraband or subject to forfeiture, or the government's need for the property as evidence continues." *United States v. Van Cauwenberghe*, 934 F.2d 1048, 1061 (9th Cir. 1991). If the court reaches the merits of "a motion for return of property [that] is made before an indictment is filed (but a criminal investigation is pending), the movant bears the burden of proving both that the seizure was illegal and that he or she is entitled to lawful possession of the property." *United States v. Martinson*, 809 F.2d 1364, 1369 (9th Cir. 1987). Nordic fails to meet either burden.

I. The products at issue were properly seized, and the *Ramsden* Factors Weigh in Favor of the Government.

a. The warrant authorized the seizure of the relevant products.

The Government did not display a callous disregard for Nordic's constitutional rights when it seized property in accordance with a lawfully obtained search warrant. Instead, the Government obtained and executed a valid search warrant at Specialty Fulfillment Center, 3 17th St. S., Nampa, ID, on September 26, 2017.

Attachment B of the search warrant sets forth property to be seized and begins with: [REDACTED]

[REDACTED] Exhibit A, ECF No. 4-3. Subsection 1(a) identifies certain products, relevant to the allegation in this motion, including: [REDACTED]

[REDACTED] *Id.* The

property to be seized by Attachment B was not specifically limited to items meant for injection or drugs only labeled as botulinum toxin. In fact, Attachment B was a non-exhaustive list over four pages describing property to be seized. That includes items such as “transportation and shipping records” and “invoices,” among many other items. *Id.*

The Neurocet, Blood Boost, ActaFLEX4x, labeling and inserts, and two folders of documents were properly seized. The three products—Neurocet, Blood Boost, and ActaFLEX4—are the focus of Nordic’s motion. As will be discussed below, those three products are all unapproved new drugs and misbranded drugs, and thus, are plainly evidence and instrumentalities relating to violations of 21 U.S.C. §331.

In addition, a plain view reading of the labeling would have alerted investigators that the products and, kits and inserts, and documentation, were within the scope of the warrant because they were unapproved new drugs. Information available on the Nordic website describes, for example, ActaFLEX4x as a product which relieves and mitigates symptoms of bodily pains to include arthritis of the fingers, hips, knees, shoulders and wrists, as well as to treat “bursitis” and “tendonitis” using a “unique transdermal delivery” via a “cetylated fatty acid complex.” *See* Exhibit 1-3, p.7-10. For the relevant time period, Nordic was not registered as a drug establishment; nor, for example, is ActaFLEX4x listed as a product by a registered drug manufacturer. *See, e.g.* Exhibit 2. A plain view of the product, would have identified the product as an unapproved new drug—bringing the property squarely within the bounds of the search warrant.²

² Arguments that the prosecutor involved in the case in any way acquiesced to allegations that the seized property was obtained unlawfully are inappropriate. As counsel is aware, the government is foreclosed from sharing or disclosing certain information; for example, the provisions of Local Criminal Rule 49.1 and Federal Rule of Criminal Procedure 6(e). *See* Exhibit D, ECF No. 4-6.

b. The movant does not have an individual interest in and need for the property that is the subject of the motion.

Nordic claims it has an individual interest in the property it seeks to have returned. This analysis is somewhat complicated by the fact that some of the labeling reads: “Distributed by: Nordic Clinical, #3 17th Ave. South, Nampa, ID 83651.” *See e.g.*, Exhibit 1-1, p. 13 and Exhibit 1-3, p. 12. The movant does not, however, make any assertions that the Specialty Fulfillment Center and Nordic Clinical are the same business.

Even assuming Nordic can show an individual interest in the property it seeks, it does not have a legitimate need for the property. Nordic sells the products at issue through its website at [REDACTED] and claims that it will lose sales of approximately \$259,000 and additional losses from expired products.³ ECF No. 4-2, p. 2. Nordic argues that the products it seeks are “essential to its business.” ECF No.4-1, p.9. The pleadings and affidavit make it clear that Nordic’s intent and need for the property is for sales, but the property is unmerchtable.

Neurocet, Blood Boost, and ActaFlex4X are unapproved new drugs and misbranded drugs, as further discussed below. *See Exhibits 1, 2.* Federal law prohibits: the introduction into interstate commerce misbranded drugs (21 U.S.C. § 331(a)); and receiving misbranded drugs in interstate commerce, and the delivery or proffered delivery thereof for pay or otherwise (21 U.S.C. § 331(c)). Nordic identifies one need for the property that is the subject of the motion—to sell it—and that is prohibited.

For the items identified as Item #29-2 folders Nordic and Item#35-Receiving Invoices for

³ The alleged loss amount is unsupported. There is no calculation or documentation to show how the number was reached, if it is based on gross revenue, and why that would be an appropriate figure. In addition, there is no information provided regarding the actual cost of the products to manufacture or the wholesale value. The Government cites the alleged loss amount as evidence of Nordic’s intent to sell unapproved new drugs and misbranded drugs.

Nordic Clinical, that property was lawfully seized pursuant to 1(b) and (c) of Attachment B. *See* ECF No. 4-3, p. 6-7. Nordic does not assert it owns Specialty Fulfillment Center. Therefore, the documents at issue are the business records of a third party, and Nordic does not have an individual interest or need for the property.

c. The movant would not be irreparably injured by denying the motion to return property.

The property at issue is not merchantable. The property that is the subject of the motion has no value as unapproved new and misbranded drugs, as set forth below in detail. As such, the issue of potential expiration fails because the products cannot be sold.⁴ Nordic has not alleged any other irreparable injury. Also, the items seized are not unique. They are primarily products and labeling. The Government did not seize property that would prevent Nordic's business from functioning, such as, production lines, buildings, wholesale ingredients, or computers. Nordic has failed to show irreparable injury if its Motion is denied.

d. The movant has an adequate remedy at law for the redress of his grievance.

As there have not been any criminal proceedings filed, it appears that this is the appropriate remedy at law for Nordic to obtain its property. The Motion, however, may be premature. The Government has an evidentiary need for the property Nordic seeks. The property is evidence and instrumentality in an ongoing criminal investigation. It was lawfully seized on September 26, 2017, and Nordic filed its motion on November 16, 2017—less than two months after the property was seized.

⁴ For two of the products, Nordic provides reports entitled "Certificate of Analysis." At the top of the certificates is information it appears was taken from a label such as the products such as code number, product, manufacture date, and an expiration date approximately two years from the manufacture date. Vitaquest Certificates, Exhibit E, ECF No. 4-7. There is no certificate for ActaFLEX4x or other evidence supporting an expiration claim.

As the *Ramsden* factors weigh in favor of the Government, the Court should decline to exercise jurisdiction over this motion. If the Court finds that it has jurisdiction over the motion, the Government asks that the motion be denied because the property cannot be returned.

II. The drugs at issue are unapproved new drugs and misbranded drugs and are not subject to return.

Nordic's Motion makes two erroneous representations about the products it wants returned. First, they represent that Neurocet and Blood Boost are "dietary supplements," providing a list of ingredients in support of this conclusory statement. Second, while they admit that ActaFLEX4x is a drug, they also claim it is lawfully "distributed under the FDA's Tentative Final Monograph," again providing a list of ingredients in apparent support of the statement. *See* ECF No. 4-1, p.7-8. Neither representation is correct. Instead, all the products are unapproved new drugs, and misbranded drugs.

a. The drugs are unapproved new drugs and misbranded Drugs.

At the outset, an overview of the legal framework applicable to all the products at issue is helpful.

Under the federal Food, Drug, and Cosmetic Act (FDCA), "drugs" are defined as, among other things, articles intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals (21 U.S.C. § 321(g)(a)(B)); articles (other than food) intended to affect the structure or function of the body of man or other animals (21 U.S.C. § 321(g)(1)(C)); or articles intended for use as components of other drugs (21 U.S.C. § 321(g)(1)(D)). Thus, a product is a "drug" not because of its ingredients, but what it is intended to be used for (although the ingredients may help establish the intended use).

Under the FDCA, a "new drug" is defined as any drug, "the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and

experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof" 21 U.S.C. § 321(p). By law, a manufacturer must obtain FDA approval of a new drug application ("NDA") or an abbreviated new drug application ("ANDA") for each new drug before it may legally be introduced into interstate commerce. 21 U.S.C. § 355(a). The introduction of an unapproved new drug into interstate commerce is prohibited by 21 U.S.C. § 331(d).

In order for a drug to be generally recognized as safe and effective (GRASE) under particular conditions of use, and thus not a "new drug," the drug must satisfy three criteria:

1. The specific drug product must have been subjected to adequate and well-controlled clinical investigations that establish the product as safe and effective under the proposed conditions of use.
2. Those investigations must have been published in the scientific literature available to qualified experts.
3. Qualified experts must generally agree, based on those published studies, that the product is safe and effective under its proposed conditions of use.

See Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 629-634 (1973); *United States v. Rutherford*, 442 U.S. 544 (1979).

Under the FDCA, "dietary supplement" means a product (other than tobacco)

- 1) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
 - a. a vitamin;
 - b. a mineral;
 - c. an herb or other botanical; an amino acid;
 - d. a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
 - e. a concentrate, metabolite, constituent, extract, or combination of any ingredient described above; AND
- 2) Is intended for ingestion, AND
- 3) Is labeled as a dietary supplement.

21 U.S.C. § 321(ff).

However, a product that might otherwise meet the definition of a "dietary supplement" is

a drug—and regulated as a drug, not a dietary supplement--if it meets the drug definition in 21 U.S.C. § 321(g).⁵ Under the FDCA, the "intended use" of a product is the ultimate key to determining into which category that product falls, and how it is regulated by FDA.

“Intended Use” means the objective intent of the persons legally responsible for the labeling of that article. The intent is determined by such persons' expressions, or can be shown by the circumstances surrounding the distribution of the article, such as labeling claims; advertising matter; oral or written statements by such persons or their representatives; or circumstances that the article was, with the knowledge of such persons or their representatives, offered and used for a purpose for which it was neither labeled nor advertised. 21 C.F.R § 201.128. Thus, if an ingestible product, labeled a “dietary supplement,” is intended by its distributor to cure, mitigate, treat or prevent disease in man, it is a drug—even if the product labeling also includes disclaimers about the intent to cure, mitigate, treat, or prevent disease. *Church of Scientology v. Richardson*, 437 F.2d 214 (9th Cir. 1971) (“Furthermore, labels of disclaimer are not controlling, but are to be considered together with any extrinsic evidence of the device's intended use (e. g. publications, advertisements, etc.)” (citing *Alberty Food Prod's v. United States*, 194 F.2d 463 (9th Cir. 1952))).

Also under the FDCA, “label” means a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term “labeling” is defined more broadly as all labels and other printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m). It is unnecessary for the matter

⁵ Note that one of the definitions for “drug,” says that “articles (*other than food*) intended to affect the structure or function of the body of man” are drugs. (21 U.S.C. § 321(g)(1)(C), emphasis added). Distributors of dietary supplements, which are a subset of food, are allowed to make structure/function claims for their products under certain conditions.

to have been physically attached to the drug or to have been shipped at the same time or with the drug to constitute “labeling.” If such matter is provided as part of an integrated distribution program pertaining to a drug and explains the uses of the drug, then it “accompanies” the drug and constitutes “labeling.” *United States v. Kordel*, 335 U.S. 345 (1948); *United States v. Urbuteit*, 335 U.S. 355 (1948). Indeed, information on a company’s website from which the product is marketed or sold can constitute “labeling” if such information is provided as part of an integrated distribution program with respect to the drug.⁶

All manufacturers, foreign and domestic, of drugs intended for distribution in the United States are required to register their manufacturing establishments, and are required to annually list every drug that they manufacture in each facility. 21 U.S.C. §360(b), (i), and (j). The failure of such persons to register or list is a crime. 21 U.S.C. §331(p).

Drugs are misbranded if, among other things: Its labeling is false or misleading in any particular; or If it was not manufactured, prepared, propagated, compounded or processed in a registered establishment under §360, or was not included in a list required by §360(j). 21 U.S.C. § 352(a) and (o). The introduction into interstate commerce of misbranded drugs is a crime (21 U.S.C. § 331(a)), as is the receipt of misbranded drugs in interstate commerce, and the delivery or proffered delivery thereof for pay or otherwise (21 U.S.C. § 331(c)).

i. Neurocet

Nordic labels their product Neurocet as a “dietary supplement,” and their Motion suggests that providing a list of ingredients for the product will establish that claim. However, in this case, the ingredients are irrelevant to the determination of whether Neurocet meets the

⁶ Websites associated with a manufacturer or distributor may also be the source of finding that entity’s intended uses of their products.

statutory definition of a “dietary supplement,” because the objective intended uses of Neurocet include the cure, mitigation, treatment, or prevention of disease in man. These intended uses make Neurocet a drug.

Evidence establishing that the intended use of Neurocet is to cure, mitigate, treat or prevent disease is abundant. Among the claims for the product on its website, which constitutes labeling for Neurocet, even today are:

Neurocet fights pain on three fronts for total body pain relief. First, it pumps up your brain’s own endorphins, giving them 48 times the pain- relieving power of morphine. Second, it inhibits collagen breakdown for stronger joints. Third, it suppresses inflammation, which can cause heat pain and swelling. By suppressing this inflammation, Neurocet reduces pain and stiffness, which can be especially helpful for those suffering from arthritis.

Neurocet helps get rid of pain all over your body! This includes, but is not limited to, pain such as: back pain, migraine headaches, joint pains, muscle aches, fibromyalgia, chronic pain, rheumatoid arthritis, osteoarthritis, whiplash, upper back pains, aching knuckles, premenstrual cramps and addictive withdrawal pain.

Exhibit 6.

Even more claims that Neurocet cures, mitigates, treats or prevents disease were in promotional flyers that were sent as part of Nordic’s integrated marketing for Neurocet:

“Neurocet blocks collagen breakdown and soothes inflammation” Additional claims such as, “Neurocet's APRESFLEX: Stops joint destruction by blocking collagen breakdown in your cartilage and connective tissues” and “Neurocet's Fruitex-B directly suppresses the inflammation that underlies most pain” are included.

There are no adequate and well-controlled clinical investigations of Neurocet for any purpose whatsoever that have been published in the scientific literature available to qualified experts. *See* Exhibits 1, 1-1. Therefore, Neurocet is both a drug and a new drug under the FDCA, and the statutes and regulations governing the marketing of drugs for sale in the United

States apply to this product. Labeling this drug a “dietary supplement” is false and misleading.

A search of the FDA’s drug approval databases reveal that Neurocet is not the subject of any of the kinds of new drug approvals described by 21 U.S.C. § 355. *Id.* Neither Nordic Clinical, Inc., nor the distribution center at 3 17th St. S., Nampa, ID is registered with FDA as a drug manufacturer. *See* Exhibit 2. Moreover, no drug establishment, foreign or domestic, has listed Neurocet as a drug it manufactures for sale in the United States.⁷ *Id.*

Based on the above analysis, Neurocet is an unapproved new drug, and is misbranded in that its labeling is false and misleading (21 U.S.C. § 352(a)), and it is manufactured in an unregistered drug establishment and is not listed by any registered drug manufacturer (21 U.S.C. § 352(o)). The introduction into interstate commerce of Neurocet did, and would, violate 21 U.S.C. §§ 331(a) and (d).⁸

ii. Blood Boost

Nordic also labels their “Blood Boost” product as a “dietary supplement,” and again, their Motion seems to suggest that providing a list of “legal” ingredients in that product settles that issue. However, as with the Neurocet product, the objective intended uses of “Blood Boost” are clearly the cure, mitigation, treatment, or prevention of disease in man. These intended uses make “Blood Boost” a drug.

The immediate label on “Blood Boost” is benign enough. But claims that this product cures, mitigates, treats, or prevent disease are quickly found in labeling and promotional material

⁷ Under 21 U.S.C. §360(i)(1)(A)(i)), a foreign manufacturer of drugs to be imported into the United States, in addition to registering, must provide FDA with the name and address of its U.S. agent and the name of any known importer of the drug in the United States.

⁸ Moreover, the receipt in interstate commerce of Neurocet by Specialty Fulfillment Center from Nordic Clinical, and the delivery or proffered delivery of those products to consumers for pay or otherwise, violated and would violate 21 U.S.C. §331(c).

for the product. For example, on the website from which the product is sold even today is a link to where Nordic compares the product to FDA-approved drugs intended to treat erectile dysfunction:

N-O Blood Boost works to restore nitric oxide levels in the body. Improving N-O availability often resolves erectile dysfunction. In fact, the popular erectile dysfunction drugs Viagra, Cialis and Levitra work on nitric oxide pathways to increase blood flow to the penis and substantially improve erections and sexual performance.⁹

Exhibit 6, p.2; *see also* Exhibit 6, p.1 (containing additional labeling).¹⁰

Even more blatant claims for treating medical conditions are made in a booklet that Nordic provides customers about Blood Boost. One of which was mailed to a private citizen who provided it to law enforcement and it was given to an FDA Office of Criminal Investigation agent prior to the issuance of the search warrant.¹¹ Exhibit 3. The twenty-seven page booklet is replete with claims for the product (which constitutes labeling for Blood Boost): “The Cure for Disease as We Know It!” and “Kill bacteria and other dangerous organisms.” *Id.* Blood Boost is also claimed to “Relax and Expand arteries” and also “Lowers blood pressure! Reduces coronary artery disease risk! Helps prevents hardening of the arteries!” *Id.*

These types of claims continue throughout the booklet. “Fantastic for your blood pressure - your doctor will be STUNNED!” and “like magic—your blood vessels expand by 62 percent to boost circulation throughout your entire body (Yes- 62 percent! It’s clinically

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¹¹ Interestingly, the return address on this booklet was “Nordic Clinical, [REDACTED] Fort Lauderdale, FL,” which appears to be the business premises of “Pak Mail,” a copying, mailbox rental, and shipping services business, as well as a “virtual office” business:

proven!”). *Id.* (emphasis in original). These are only a few of the literally dozens of claims in the booklet regarding the intended use of Blood Boost to cure, mitigate, treat, and prevent a variety of diseases; clearly, it is a drug.

There are no adequate and well-controlled clinical investigations of Blood Boost for any purpose whatsoever that have been published in the scientific literature available to qualified experts. *See* Exhibits 1, 1-2. Therefore, it is also a new drug under the FDCA, the statutes and regulations governing the marketing of drugs for sale in the United States apply to this product. Labeling this drug a “dietary supplement” is false and misleading.

A search of the FDA’s drug approval databases reveal that Blood Boost is not the subject of any of the kinds of new drug approvals described by 21 U.S.C. § 355. *Id.* Neither Nordic Clinical, Inc., nor the distribution center at 3 17th St. S., Nampa, ID is registered with FDA as a drug manufacturer. *See* Exhibit 2. Moreover, no drug establishment, foreign or domestic, has listed Blood Boost as a drug it manufactures for sale in the United States. *Id.*

Based on the above analysis, Blood Boost is an unapproved new drug, is misbranded in that its labeling is false and misleading (21 U.S.C. § 352(a)), and it is manufactured in an unregistered drug establishment and is not listed by any registered drug manufacturer (21 U.S.C. § 352(o)). The introduction into interstate commerce of Blood Boost did, and would, violate 21 U.S.C. §§ 331(a) and (d).¹²

iii. ActaFLEX4x

Nordic’s Motion represents that its topical drug ActaFLEX4x “...is otherwise distributed under the FDA’s Tentative Final Monograph, 48 Fed Reg. 3852 (Feb. 8, 1983),” and thus a

¹² *See* footnote 8; the same §331(c) violation would apply to Specialty’s shipments of Blood Boost.

lawfully marketed over-the-counter (OTC) drug. ECF No.4-1, p.7. However, ActaFLEX4x does not comport with the referenced Tentative Final Monograph (TFM).

The OTC Drug Review program was created by FDA in 1972 to facilitate the efficient review of hundreds of thousands of OTC drugs already on the market at that time. Rather than approve each individual product, as is done for prescription drugs and certain OTC drugs, the OTC Drug Review developed monographs for various therapeutic categories (e.g. external analgesics, cough/cold products). The monographs established conditions, such as active ingredients, indications, dosage form and labeled directions, under which an OTC drug is generally recognized as safe and effective (GRASE). An OTC drug that meets the specific conditions contained in a monograph is not required to be approved by FDA before marketing.

The OTC Drug Review was intended to be a three-step, public notice and comment rulemaking process. As originally implemented, the process began with publication in the Federal Register of reports from an outside panel of experts. These reports were published in Advance Notices of Proposed Rulemakings, or ANPRs. Public comments on these reports were submitted by the drug industry, by medical professionals, and by consumers – anyone with an interest in the topic of the report could submit comments. FDA considered the reports, comments, any new data and information, revised the ANPR accordingly, and published the revisions as a proposed rule. The proposed rule is also known as the TFM.

In response to the TFM, a second round of comments was received and evaluated. Following submission of comments to the TFM, the last step of the process was for FDA to analyze the comments and data that were submitted in response to the TFM, and to revise the monograph and publish it as a final rule. Once published, the final monograph would contain the regulations that establish the conditions under which a category of OTC drugs is considered

GRASE. The final monographs would then be published in the Code of Federal Regulations in Title 21, Food and Drugs.

Although some monographs in the OTC drug review were finalized using this three-step public notice and comment rulemaking process, for many other monographs, various issues have delayed the publishing of a final rule. Thus, for more than 30 years, many categories of OTC products have remained covered by the TFM. Pending a final monograph/rule, FDA generally does not object to the marketing of products that meet both the formulation and labeling required described in the TFM. But for products which do not comport with a final monograph or TFM, the regulatory scheme for new drugs is applied.

Drug products intended for external (generally topical) analgesic indications such as the relief of pain are evaluated under the TFM for OTC External Analgesics (48 Federal Register (FR) 5852, February 8, 1983). *See* 48 FR 5709, pp. 5852-69, Exhibit 4.

At first glance, ActaFLEX4x might appear to be within the TFM. The immediate product label says that the active ingredient in ActaFLEX4x Pain Relief Cream is menthol 1.25%, which is a proposed acceptable ingredient in the TFM. The indications of use found on the product label are also included in the TFM.

However, as explained above, there is more to the *labeling* of ActaFLEX4x than just what appears on the immediate packaging, and here, that labeling removes ActaFLEX4x from the umbrella of the TFM. Among those labeling issues: There are additional indications for use on Nordic's website that are not in the TFM, including treating "bursitis" and "tendonitis." *See* Exhibit 1-3, p. 7. The website also makes claims that the product has a "unique transdermal delivery," which is a novel dosage form that requires NDA approval (21 C.F.R. § 310.3(h)(5)) and is not covered under the TFM. *See* Exhibit 1-3, p. 10. The website says use of the product

has “cumulative benefits by using it over a 30-day period.” *Id.* at p.9. The TFM does not provide for any “cumulative” effects claims.

In addition; ActaFLEX4x is also outside the TFM, as well as being misbranded under 21 U.S.C. § 352(a), because while the Drug Facts lists “menthol 1.25%” as the sole active ingredient, the website labeling describes “cetylated fatty acid complex,” a labeled inactive ingredient, in a role greater than its inactive purpose. *Id.*; see 21 C.F.R. § 201.10(c)(4) (“The labeling of a drug may be misleading by reason (among other reasons) of: . . . The featuring in the labeling of inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the formulation.”) Based on the labeling on Nordic’s website beginning with the title “The ActaFLEX 4x Secret” (Exhibit 1-3, p. 9), “cetylated fatty acid complex” is intended as an active ingredient, defined at 21 CFR § 201.66(b)(2) as “any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.” Inclusion of “cetylated fatty acid complex” in this role also causes ActaFLEX4x to fall outside of the TFM; it is thus a new drug.

There are no adequate and well-controlled clinical investigations of ActaFLEX4x for any purpose whatsoever that have been published in the scientific literature available to qualified experts. *See* Exhibit 1.

Since ActaFLEX4x is both a drug and a new drug under the FDCA, the statutes and regulations governing the marketing of drugs for sale in the United States apply to this product.

A search of the FDA’s drug approval databases reveal that ActaFLEX4x is not the

subject of any of the kinds of new drug approvals described by 21 U.S.C. § 355. *Id.* As previously noted, neither Nordic Clinical, Inc., nor the distribution center at 3 17th St. S., Nampa, ID is registered with FDA as a drug manufacturer. *See* Exhibit 2. Moreover, no drug establishment, foreign or domestic, has listed ActaFlex4x as a drug it manufactures for sale in the United States. *Id.*

Based on the above analysis, ActaFLEX4x is an unapproved new drug, and is misbranded in that its labeling is false and misleading (21 U.S.C. § 352(a)), and it is manufactured in an unregistered drug establishment and is not listed by any registered drug manufacturer (21 U.S.C. § 352(o)). The introduction into interstate commerce of ActaFLEX4x did, and would, violate 21 U.S.C. §§ 331(a) and (d).¹³

b. The drug products seized are not subject to return.

A Rule 41(g) motion should be denied "if the defendant is not entitled to lawful possession of the seized property, the property is contraband or subject to forfeiture, or the government's need for the property as evidence continues." *United States v. Van Cauwenberghe*, 934 F.2d 1048, 1061 (9th Cir. 1991).

i. The drug products seized are contraband.

A Motion for Return of Property under Rule 41(g) cannot be granted when the property in question is contraband, and should never be returned even to a rightful owner. *United States v. Jeffers*, 342 U.S. 48 (1951). *Trupiano v. United States*, 334 U.S. 699, 710 (1948); Fed. R. Crim. P. 41(g) (advisory committee note accompanying 1972 amendments: "the judge in the district of seizure does not have to decide the legality of the seizure in cases involving

¹³ See footnote 8; the same §331(c) violation would apply to Specialty's shipments of ActaFLEX4x.

contraband which, even if seized illegally, is not to be returned.”). The rule against returning contraband is so broad that it cannot be returned even if the seizure itself was unlawful.

Trupiano, 334 U.S. at 710.

Contraband is "any property which is unlawful to produce or possess. Things and objects outlawed and subject to forfeiture and destruction upon seizure. . . . Goods exported from or imported into a country against its laws." BLACK'S LAW DICTIONARY, 322 (Sixth Edition, 1990). In *Bennis v. Michigan*, the dissent identified different types of contraband, pertinent to this matter is: "The first category—pure contraband—encompasses items such as adulterated food, sawed-off shotguns, narcotics, and smuggled goods. With respect to such "objects the possession of which, without more, constitutes a crime," the government has an obvious remedial interest in removing the items from private circulation, however blameless or unknowing their owners may be." *Bennis v. Michigan*, 516 U.S. 442, 459 (1996) (J. Stevens, dissenting) (citation omitted). *See also Myers v. Malone & Hyde*, 173 F.2d 291, 295 (8th Cir. 1949) ("But being misbranded [the canned tomatoes] were subject to confiscation by the United States and could not be legally held or sold by the buyer. They were contraband under the law of the United States, and as such were not merchantable.").

In this case, the products at issue— Neurocet, Blood Boost and ActaFLEX4x-- are unapproved new drugs and misbranded drugs, shipped in interstate commerce to Idaho in violation of 21 U.S.C. §§ 331(a) and (d), and proffered for sale from that location in violation of 21 U.S.C. § 331(c). Indeed, Nordic's own Motion admits that Nordic wants these drugs returned so that they can continue to introduce them into interstate commerce to fulfill customer orders, which would constitute further criminal acts.

ii. The property is evidence in an ongoing investigation.

Another factor for consideration in *Van Cauwenberghe* is whether government's need for the property continues. The government has had these products for approximately two months. At this time, the government seeks to maintain the lawfully seized property as it continues a criminal investigation.

III. Under the doctrine of unclean hands, the Court should not provide the relief requested by Nordic.

Because Nordic's Motion asks for equitable relief, all the principles of equity apply. This doctrine "provides that a party to a lawsuit may not obtain the relief it seeks if it has engaged in wrongful conduct." *Smith v. United States*, 293 F.3d 984, 988 (7th Cir. 2002).

"[H]e who comes into equity must come with clean hands. This maxim is far more than a mere banality. It is a self-imposed ordinance that closes the doors of a court of equity to one tainted with inequity or bad faith relative to the matter in which he seeks, however improper may have been the behavior of the defendant." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945). *See also Adler v. Fed. Republic of Nigeria*, 219 F.3d 869, 877 (9th Cir.2000); *Danjaq LLC v. Sony Corp.*, 263 F.3d 942, 956 (9th Cir. 2001).

As demonstrated above, these drugs are contraband – misbranded and unapproved new drugs unlawfully shipped in interstate commerce. Nordic asks the court to ignore the illegality of its business and the contraband nature of these goods, and simply return these unmerchantable drugs so they may continue their unlawful conduct. "[E]quitable relief *will* be refused if it would give the plaintiff a wrongful gain." *Scheiber v. Dolby Laboratories, Inc.*, 293 F.3d 1014, 1021-22 (7th Cir., 2002, emphasis added). A court should always "withhold an equitable remedy that would encourage, or reward (and thereby encourage), illegal activity." *Shondel v. McDermott*, 775 F.2d 859, 868 (7th Cir. 1985). "Public policy . . . makes it *obligatory* for courts to deny a

plaintiff relief once his 'unclean hands' are established" *Gaudiosi v. Mellon*, 269 F.2d 873, 881-82 (3d Cir. 1959), *cert. denied*, 361 U.S. 902 (1959) (emphasis added).

CONCLUSION

The Court should deny the petition because the property that is the subject of the request to return was lawfully seized pursuant to a search warrant, the *Ramsden* factors weigh in the Government's favor, and the products are unapproved new drugs and misbranded drugs and cannot be returned. Likewise, under the equitable doctrine of unclean hands, this court should deny Nordic this relief, since the very business it conducts is unlawful, and the product it distributes cannot be legally sold. For all the foregoing reasons, the United States respectfully requests that the Court deny the Motion.

Respectfully submitted this 1st of December, 2017.

BART M. DAVIS
UNITED STATES ATTORNEY
By:

/s/ _____
DARCIN WARD
Assistant United States Attorney

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 1, 2017, the foregoing **GOVERNMENT'S RESPONSE TO NORDIC CLINICAL'S MOTION FOR RETURN OF PROPERTY PURSUANT TO FED. R. CRIM. P. 41(g)** was electronically filed with the Clerk of the Court using the CM/ECF system, and that a copy was served on the following parties or counsel by:

<p>Scott McKay (ISB#4309) NEVIN, BENJAMIN, McKAY & BARTLETT 303 West Bannock Boise, Idaho 83701 Telephone: (208) 343-1000 smckay@nbmlaw.com</p>	<p><input type="checkbox"/> United States Mail, postage prepaid <input type="checkbox"/> Fax <input checked="" type="checkbox"/> ECF filing <input type="checkbox"/> E-mail</p>
<p>Andrew B. Lustigman OLSHAN FROME WOLOSKY, LLP 1325 Avenue of the Americas New York, New York 10019 Telephone: (212) 451-2300 alustigman@olshanlaw.com</p>	

Darci N. Ward

EXHIBIT E

REDACTED PUBLIC VERSION

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UNITED STATES ATTORNEY
DARCI N. WARD, IDAHO STATE BAR NO. 8852
ASSISTANT UNITED STATES ATTORNEY
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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

IN RE SEARCH OF SPECIALTY
FULFILLMENT CENTER,
3 17TH AVE. S, NAMPA, ID

NORDIC CLINICAL, INC.,

Petitioner,

vs.

UNITED STATES OF AMERICA,

Respondent.

Case No. 17-mc-09979-CWD

RESPONSE TO SUPPLEMENTAL
DECLARATION OF ANDREW B.
LUSTIGMAN IN FURTHER SUPPORT OF
NORDIC'S MOTION FOR RETURN OF
PROPERTY UNDER RULE 41(g)

The United States of America, by and through Bart M. Davis, United States Attorney, and the undersigned Assistant United States Attorney for the District of Idaho, submits this response to the Supplemental Declaration of Andrew B. Lustigman in Further Support of Nordic's Motion for Return of Property Under Rule 41(g) ("Declaration"). (ECF No. 18.)

Following the evidentiary hearing on December 11, 2017, Nordic Clinical (“Nordic”) was asked to provide additional information regarding its ownership of the return of property motion and identifying manufacturers of the unapproved new drugs and misbranded drugs. The Declaration discusses four products: Neurocet, Blood Boost, GSH-3, and ActaFLEX4x. The Government did not seize any of the GSH-3 product, so it is not addressed in this Response.¹

Neurocet and Blood Boost are unapproved new drugs and are misbranded in that the labeling is false and misleading (21 U.S.C. § 352(a)). (See ECF No. 8, p. 8-15.) Both products are manufactured in an unregistered drug establishment and are not listed by any registered drug manufacturer (21 U.S.C. § 352(o)). No information provided in the Declaration shows otherwise.

ActaFLEX4x does not comport with the External Analgesic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph (“TFM”) for multiple reasons. The Declaration attempts to overcome the fact that ActaFLEX4x is misbranded pursuant to 21 U.S.C. § 352(a). The Drug Facts on ActaFLEX4x list “menthol 1.25%” as the sole active ingredient, but the labeling and the Declaration identify Celadrin as an active ingredient. (See ECF No. 18, ¶ 12, 16.) In addition, the identification of Celdarin as an active ingredient also causes it to fall outside the TFM. (See ECF No. 8, p. 17-19.) The Declaration asserts: “the Government takes issue with the active ingredient ‘Celadrin’ – a fatty acid complex which contains the form of menthol. . . .” (*Id.*) This assertion is problematic for a number of reasons.

First, menthol is not a fatty acid; and, therefore, a “fatty acid complex” could not properly describe a blend of items containing menthol. Second, [REDACTED] is the

¹ The Inventory of Evidence from the search warrant lists GSH-3 kitted inserts. The Government maintains its position set forth in the Response to Nordic’s Motion Pursuant to Rule 41(g) (ECF No. 8) and at the evidentiary hearing on December 11, 2017.

registrant of a finished drug with the proprietary name of Celadrin, which is registered as meeting the OTC monograph for topical pain creams and identified by NDC 65643-406. *See* Exhibit 1. An ingredient cannot meet a monograph. The monograph describes finished drugs for specific medical indications, it does not describe ingredients. Third, the assertion that ActaFLEX4x contains Celdarin as an active ingredient directly conflicts with the label of ActaFLEX4x that identifies Celdarin as an inactive ingredient. (ECF No. 19-3, p. 5.) Thus, the declarations, representations, and labeling are in conflict.

The Declaration asserts that ActaFLEX4x is the finished drug product Celdarin that meets the TFM. If that is true, then ActaFLEX4x is misbranded pursuant to 21 U.S.C. § 352(a). If Nordic asserts that the ActaFLEX4x label is correct and Celdarin is an inactive ingredient, then ActaFlex4x is not only misbranded; it is also outside the TFM. In addition, if Celdarin is one ingredient mixed with a number of ingredients, then it is not the [REDACTED] product that is produced as NDC 65643-406.

The NDC 65643-406 that appears on some of the seized ActaFLEX4x tubes is a NDC for a finished product with the proprietary name Celadrin that was registered by [REDACTED]. The Declaration concedes that Nordic should be using their own NDC on the ActaFLEX4x. The Declaration attempts to dismiss this noncompliance, stating “this, in my judgment, is a technical deficiency.” (ECF No. 18, ¶ 15.) Nordic cannot choose to comply with certain laws while simultaneously judging their violations of other laws as “technical deficiencies.” In fact, using the NDC from [REDACTED] obviates traceability to the manufacturer, as this case well demonstrates. Using the [REDACTED] NDC suggests [REDACTED] made the finished product, and the Declaration indicates that Tri-Pharma was contracted to manufacture the product. (ECF No. 18, ¶ 14.) The printout from the FDA’s National Drug Code Directory further makes this point. Attached to the

Declaration as Exhibit H, the printout shows three different companies that have listed the proprietary name of Celadrin, but each have their own NDC. (ECF No. 18-8.)

Special Agents with the FDA Office of Criminal Investigations spoke to some representatives from [REDACTED] on December 19, 2017. [REDACTED] representatives indicated that [REDACTED] manufactured a cream containing the ingredient Celadrin for a company that declared bankruptcy about twelve to eighteen months ago. During the bankruptcy stage, that company introduced [REDACTED] to one of its largest customers, Tri-Pharma. [REDACTED] subsequently used the remaining finished product originally produced for the bankrupt company to package ActaFLEX4x for Tri-Pharma. [REDACTED] manufactured 2 batches of ActaFLEX4x for Tri-Pharma. The orders included one batch for 5,500 tubes and another for 19,500 tubes. The tubes were filled at [REDACTED] and the finished product was shipped to Specialty Fulfillment Center, 3 17th Ave South, Nampa, ID 83651. The representatives from [REDACTED] were not familiar with the names Nordic Clinical or [REDACTED] and did not have any memory of business dealings with the companies.² Separately, [REDACTED] registered NDC 65643-406 as a manufacturer, packager, and filler of the product Celadrin in 2009. *See* Exhibit 1.

The Declaration represents that Tri-Pharma was “contracted to manufacture ActaFLEX4x for Nordic.” (ECF No. 18, ¶ 14.) The Drug Registration and Listing electronic database does not show Tri-Pharma as having registered any establishment as a drug establishment. Even assuming Tri-Pharma was contracted to manufacture ActaFLEX4x, the invoice used by Nordic to prove this relationship is from November 2015. (ECF No. 18-5.) Nordic has failed to provide an invoice showing any evidence of this manufacturing relationship within the past two years. The

² [REDACTED] representatives indicated it was an error for them to overlook the use of their NDC printed on the label and not verify its legitimacy.

provided invoice is billed to [REDACTED] Nordic Clinical and the product is to be shipped to the Specialty Fulfillment Center, 3 17th Ave. South, Nampa, ID. In November 2016, [REDACTED] was identified as a parent corporation of Nordic Clinical. See Exhibit 2. The exemplary contract provided by Nordic as evidence of their relationship with Specialty Fulfillment Center states that “[Specialty Fulfillment Center] will develop and manage a program for [REDACTED] P products.” (See ECF No. 18-9, p. 3.) No additional information is provided regarding [REDACTED] and their relationship to Nordic.

Respectfully submitted, the 26th day of December, 2017.

Darci N. Ward
Assistant United States of America

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 27, 2017, the foregoing RESPONSE TO SUPPLEMENTAL DECLARATION OF ANDREW B. LUSTIGMAN IN FURTHER SUPPORT OF NORDIC'S MOTION FOR RETURN OF PROPERTY UNDER RULE 41(g) was electronically filed with the Clerk of the Court using the CM/ECF system, and that a copy was served on the following parties or counsel by:

<p>Scott McKay (ISB#4309) NEVIN, BENJAMIN, McKAY & BARTLETT 303 West Bannock Boise, Idaho 83701 Telephone: (208) 343-1000 smckay@nbmlaw.com</p> <p>Andrew B. Lustigman OLSHAN FROME WOLOSKY, LLP 1325 Avenue of the Americas New York, New York 10019 Telephone: (212) 451-2300 alustigman@olshanlaw.com</p>	<p><input type="checkbox"/> United States Mail, postage prepaid</p> <p><input type="checkbox"/> fax</p> <p><input checked="" type="checkbox"/> ECF filing</p> <p><input type="checkbox"/> email</p>
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Darci N. Ward

EXHIBIT F

REDACTED PUBLIC VERSION

REDACTED

REDACTED PUBLIC VERSION

EXHIBIT C

REDACTED

REDACTED PUBLIC VERSION

EXHIBIT H

REDACTED PUBLIC VERSION

January 8, 2017


VIA E-MAIL

Mamie Kresses, Esq.
Edward Glennon, Esq.
United States Federal Trade Commission
Washington, D.C. 20580
e-mail: mkresses@ftc.gov; eglennon@ftc.gov

Re: CIDs Directed to Nordic Clinical, Inc. and Encore Plus Solutions, Inc.

Dear Mamie and Edward:

I am writing to follow up on the meet-and-confer call we conducted on Friday, January 5th.

On August 18, 2017, this office, on behalf of our clients, responded to the Federal Trade Commission's initial CIDs. 



We learned of these matters as follows:





All of these developments occurred after the initial CID responses were made. In light of these facts, and in order to avoid the very real Fifth Amendment concerns raised by the FTC's attempts to conduct civil deposition in the face of multiple parallel criminal investigations, we suggest the FTC withdraw the two CIDs and agree to one of the two following alternatives:

(a) Stay all FTC administrative proceedings until the resolution of the criminal investigations. My clients will enter into a tolling agreement so that that FTC cannot be prejudiced by the passage of time; or

(b) My clients will answer written interrogatories to be propounded by the FTC in lieu of the depositions, with the understanding and agreement that my clients will be allowed to assert the Fifth Amendment and potentially relevancy in response to individual questions. No waiver of any rights against self-incrimination shall be inferred by the written answers or by the act of answering some or all questions. My clients will enter into a limited tolling agreement similar to the one we agreed to in July of last year.

While you are considering these alternatives, please confirm that the FTC has agreed to extend the time in which our clients have to file a motion to quash, which we calculate as being January 12, 2018.

Very truly yours,

/s/ Andrew B. Lustigman

Andrew B. Lustigman

Shaffer, Scott A.

From: Kresses, Mamie <MKRESSES@ftc.gov>
Sent: Tuesday, January 09, 2018 3:11 PM
To: Lustigman, Andrew B.; Shaffer, Scott A.
Cc: Glennon, Edward; Northrop, Kathleen M.
Subject: RE: Following up on your 01.08 letter re CIDs Directed to Nordic Clinical, Inc. and Encore Plus Solutions, Inc.pdf

Andy,

As you know, upon receipt of your letter attached to your email below, we left you a voicemail yesterday in an attempt to follow up on your proposals therein. Since we have not heard back from you, this email provides our response. In your letter, you state that you have recently learned of several possible criminal investigations "covering the same entities and/or the sale or marketing of at least some of the nutritional supplements covered by" the Commission's CIDs for investigational hearings of your clients, Encore Plus Solutions and Nordic Clinical. You propose that the Commission either stay its proceedings pending the resolution of all criminal investigations or allow your clients to propound written answers in lieu of oral testimony. You also ask that the FTC staff consider an extension of the time for your clients to file a motion to quash the CIDs.

We have discussed your proposals with Associate Director Mary Engle, and she is not willing to accept them. Concerning your proposal to suspend our investigation during the pendency of any criminal investigations, we do not know how long any criminal investigations might take and we do not wish to unnecessarily delay moving forward with our own investigation. Furthermore, the CIDs call for the testimony only of corporate entities, which legally may not assert a right against self-incrimination under the 5th Amendment. Regarding your proposal to provide written answers in lieu of conducting the investigational hearings, written testimony would not provide us with the detail and ability to conduct immediate follow-up questioning that we believe is necessary to expeditiously and efficiently conduct our investigation.

With regard to the deadline to file a motion to quash, Ms. Engle has authorized us to tell you that she is willing to extend the deadline until January 17 provided that you first confirm in writing that any such motion to quash will be based on substantive legal arguments and not on procedural arguments such as service of process or other non-substantive matters.

Please let us know whether you wish for us to seek Ms. Engle's agreement to this modification of the time for filing such a motion.

Regards,
Mamie

From: Northrop, Kathleen M. [mailto:KNorthrop@olshanlaw.com]
Sent: Monday, January 08, 2018 12:00 PM
To: Glennon, Edward; Kresses, Mamie
Cc: Lustigman, Andrew B.
Subject: Emailing: Ltr. to Mamie Kresses and Edward Glennon re CIDs Directed to Nordic Clinical, Inc. and Encore Plus Solutions, Inc.pdf

THIS MESSAGE IS BEING SENT ON BEHALF OF ANDREW B. LUSTIGMAN

Legal Secretary

OLSHAN

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Shaffer, Scott A.

From: Glennon, Edward <eglennon@ftc.gov>
Sent: Thursday, March 15, 2018 7:08 PM
To: Shaffer, Scott A.; Lustigman, Andrew B.; Kresses, Mamie
Subject: RE: Nordic Clinical, Inc., LLC and Encore Plus Solutions, Inc.

Scott,

We are ok with your position on the meet-and-confer. Also, we understand from your email that you plan to re-file your petition to quash the CIDs; please let us know if that is not correct.

Best,

Ed

Edward Glennon
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Bureau of Consumer Protection
Federal Trade Commission
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Washington, D.C. 20580
Ph.: (202) 326-3126
Fax: (202) 326-3259
Email: eglennon@ftc.gov

From: Shaffer, Scott A. [mailto:SShaffer@olshanlaw.com]
Sent: Thursday, March 15, 2018 11:22 AM
To: Glennon, Edward; Lustigman, Andrew B.; Kresses, Mamie
Subject: RE: Nordic Clinical, Inc., LLC and Encore Plus Solutions, Inc.

Mamie and Ed:

We have reviewed the re-issued CIDs and, other than the issue of service to Andrew Lustigman, we have the same objections to these CIDs as previously expressed in our prior meet-and-confer efforts and the motion to quash to the prior CIDs.

As both sides are have already met and conferred on these issues in January through telephone conferences and written correspondence and the central issues remain the same (with the one small exception identified above), please accept this e-mail as our effort to meet and confer on the two re-issued CIDs.

If you believe another telephone call is nonetheless necessary, please let me know when you are available.

Thank you,

Scott A. Shaffer