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IN THE UNITED STATES DISTRICT COURT DISTRICT OF UTAH, CENTRAL DIVISION

FEDERAL TRADE COMMISSION,

: Civil No. 2:01 CV-0505ST

Plaintiff,

:

VS.

CHRISTOPHER ENTERPRISES, INC., Stipulated Final Order for Permanent

a corporation, and : Injunction and Settlement of Claims

for Monetary Relief

NORMAN BACALLA and RUTH :

CHRISTOPHER BACALLA, individually

and as officers of the corporation, : Magistrate Judge Ronald N. Boyce

Defendants. :

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), filed a Complaint for permanent injunction and other relief against Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla, pursuant to 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b).

The Commission and Defendants, without Defendants admitting liability for any of the violations alleged in the Complaint, have stipulated to the entry of the following Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief ("Order") in settlement of the Commission's complaint against Defendants. The Court, being advised in the premises, finds:

FINDINGS

- 1. This Court has jurisdiction over the subject matter of this case and jurisdiction over all parties. Venue in the District of Utah is proper.
- 2. The Complaint states a claim upon which relief can be granted, and the Commission has authority to seek the relief it has requested.
- The activities of Defendants are in or affecting commerce, as defined in 15 U.S.C.
 § 44.
- 4. Defendants waive all rights to seek judicial review or otherwise challenge or contest the validity of this Order. Defendants also waive any claim that they may have held under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action to the date of this Order.
 - 5. Each party shall bear its own costs and attorneys' fees.

6. Entry of this Order is in the public interest.

DEFINITIONS

For the purposes of this Order, the following definitions shall apply:

- 1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
- 2. "Defendants" means Christopher Enterprises, Inc., Norman Bacalla, Ruth Christopher Bacalla, and their successors, assigns, officers, agents, directors, servants, employees, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any affiliate, corporation, subsidiary, division or other device.
- 3. "Distributor" shall mean any purchaser or other transferee of any product covered by this Order who acquires such product directly or indirectly from Defendants with or without valuable consideration, and who sells, or who has sold, such product to other sellers or to consumers, including but not limited to individuals, retail stores, or catalogs.
- 4. "Food" and "drug" shall mean "food" and "drug" as defined in Section 15 of the FTC Act, 15 U.S.C. § 55(b)-(c).
- 5. "Comfrey product" shall mean any product consisting of, containing, or including, or represented by Defendants to consist of, contain, or include as an ingredient, any of the following plants, any part of the following plants, or any extract or derivative of the following plants: *Symphytum*

officinale (also known as common comfrey), Symphytum asperum (also known as prickly comfrey), or Symphytum x uplandicum (also known as Russian comfrey).

- 6. "Clearly and prominently" shall mean as follows:
- In an advertisement communicated through an electronic medium (such as a. television, video, radio, and interactive media such as the Internet, online services, and software), the disclosure shall be presented simultaneously in both the audio and visual portions of the advertisement. Provided, however, that in any advertisement presented solely through visual or audio means, the disclosure may be made through the same means in which the ad is presented. Provided, further, that in any advertisement communicated through interactive media which is presented predominantly through visual or audio means, the disclosure may be made through the same means in which the advertisement is predominantly presented. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The visual disclosure shall be of a size and shade, with a degree of contrast to the background against which it appears, and shall appear on the screen for a duration and in a location, sufficiently noticeable for an ordinary consumer to read and comprehend it. In addition to the foregoing, in interactive media, the disclosure shall also be unavoidable and shall be presented prior to the consumer incurring any financial obligation.
- b. In a print advertisement, promotional material, or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears. In multi-page documents, the disclosure shall appear on the cover or first

c. On a product label, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it and in print that contrasts with the background against which it appears. Provided, however, if a disclosure on a bottle label or package label is made in a location other than the principal display panel, the bottle label or package label shall include the statement, "See important safety warning on [insert disclosure location]" as follows: (a) in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it; (b) in print that contrasts with the background against which it appears; and (c) within a border that is a color or shade that contrasts with the background against which it appears. Provided, further, that in a multi-page insert, the disclosure shall appear on the cover page or first page.

The disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label.

- 7. A requirement that any Defendant communicate with the Commission shall mean that the Defendant shall send the necessary information via first-class mail, costs prepaid, to the Regional Director, Federal Trade Commission, Southwest Region, 1999 Bryan Street, Suite 2150, Dallas, TX 75201. Attn: FTC v. Christopher Enterprises, Inc., et al. (D. Utah).
 - 8. The term "including" in this Order shall mean "without limitation."
- 9. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I. CONDUCT PROHIBITIONS

- A. IT IS THEREFORE ORDERED that, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any comfrey product, Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla, and their successors, assigns, officers, agents, directors, servants, employees, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any affiliate, corporation, subsidiary, division or other device, are permanently restrained and enjoined:
 - From marketing such product for ingestion, for use as a suppository, or for external use on open wounds; and
 - 2. From failing to make the following disclosure, clearly and prominently, in any advertisement, promotional material, package label, and package insert for any comfrey product marketed for other external use:

WARNING: External Use Only. Consuming this product can cause serious liver damage. This product contains comfrey. Comfrey contains pyrrolizidine alkaloids, which may cause serious illness or death. This product should not be taken orally, used as a suppository, or applied to broken skin. For further information contact the Food and Drug Administration: http://vm.cfsan.fda.gov

unless Defendants possess competent and reliable scientific evidence conclusively demonstrating that the product is free of pyrrolizidine alkaloids and safe for such uses. <u>Provided, however</u>, that in the event the Food and Drug Administration issues a rule or regulation that requires a warning

or a disclosure on the labeling of products containing comfrey, Defendants may substitute that warning for the disclosure required under this Paragraph.

- B. IT IS FURTHER ORDERED that, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any comfrey product, Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla, and their successors, assigns, officers, agents, directors, servants, employees, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any affiliate, corporation, subsidiary, division or other device, are restrained and enjoined from representing in any manner, expressly or by implication, that:
 - 1. Such product is effective in the prevention, mitigation, treatment or cure of asthma, arthritis, broken bones, bronchitis, cancer, "charlie horses," colds, coughs, cramps, curvature of the spine, emphysema, headache, herpes simplex, infection, insomnia, lung congestion, multiple sclerosis, muscular dystrophy, osteoporosis, paralysis, polio, prolapsed bowel and uterus, pyorrhea, rheumatism, sore throats, spinal cancer, stroke, thrush, toothache, tuberculosis, varicose veins, or yeast infections;
 - Such product is effective in supplying all calcium needs, including all calcium needs of a developing fetus, or in restoring teeth; or
- 3. Such product is safe and effective for the uses for which it is sold; unless, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.
 - C. IT IS FURTHER ORDERED that, in connection with the manufacturing, labeling,

advertising, promotion, offering for sale, sale, or distribution of any food, drug, dietary supplement, or other health-related product or service, Defendants Christopher Enterprises, Inc., Norman Bacalla, Ruth Christopher Bacalla, and their successors, assigns, officers, agents, directors, servants, employees, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any affiliate, corporation, subsidiary, division or other device, are permanently restrained and enjoined from making any representation in any manner, expressly or by implication, about the safety, health benefits, performance, or efficacy of such product or service, unless, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II. FOOD AND DRUG REGULATIONS

- A. **IT IS FURTHER ORDERED** that nothing in this Order shall prohibit Defendants from making any representation for any product that is specifically permitted in the labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.
- B. **IT IS FURTHER ORDERED** that nothing in this Order shall prohibit Defendants from making any representation for any drug that is permitted in the labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration or under any new drug application approved by the Food and Drug Administration.

III. IDENTIFICATION OF PURCHASERS

IT IS FURTHER ORDERED that Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla shall:

- A. Within ten (10) days after entry of this Order, deliver to the Commission a list, in the form of a sworn affidavit, of all distributors who purchased on or after January 1, 1998, a comfrey product, directly from Defendants or indirectly through one of Defendants' other distributors, to the extent that such distributor is known to Defendants through a diligent search of Defendants' records, including but not limited to computer files, sales records, and inventory lists. Such list shall include each distributor's name and address, and, if available, the distributor's telephone number and email address, and the full purchase price, including shipping, handling, and taxes, of the comfrey product(s) purchased from Defendants.
- B. Within ten (10) days after entry of this Order, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers who purchased on or after January 1, 1998, a comfrey product, directly from Defendants or indirectly through one of Defendants' distributors, to the extent that such consumer is known to Defendants through a diligent search of Defendants' records, including but not limited to computer files, sales records, and inventory lists. Such list shall include each consumer's name and address, and, if available, the consumer's telephone number and email address, and the full purchase price, including shipping, handling, and taxes, of the comfrey product(s) purchased from Defendants.

IV. NOTIFICATION TO DISTRIBUTORS

IT IS FURTHER ORDERED that:

- A. Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher

 Bacalla shall not disseminate to any distributor any material containing any representation prohibited by this Order.
- B. Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla shall not, directly or indirectly, authorize any distributor to make any representation prohibited by this Order.
- C. Within ten (10) days after entry of this Order, Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla shall send by first class mail a notice, in the form shown on Appendix A, to each distributor with whom Defendants have done business since January 1, 1998, to the extent that such distributor is known to Defendants through a diligent search of Defendants' records, including but not limited to computer files, sales records, and inventory lists. The mailing shall not include any other documents. Defendants shall require each distributor to execute and return the original of the letter as a condition of remaining or once again becoming a distributor for Defendants.
- D. For a period of five (5) years following entry of this Order, Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla shall send by first class mail a notice, in the form shown on Appendix A, to each distributor with whom Defendants do business after the date of entry of this Order who has not previously received said notice. Such notice shall be sent within seven (7) days from the first shipment of Defendants' product to said distributor. The mailing shall not

include any other documents. Defendants shall require each distributor to execute and return the original of the letter as a condition of remaining or becoming a distributor for Defendants.

- E. Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher

 Bacalla shall institute a reasonable program of surveillance adequate to reveal whether any of

 Defendants' distributors are disseminating advertisements or promotional materials or making any oral

 statement that contain any representation prohibited by this Order.
- F. Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla shall terminate all sales of any food, drug, device, service, or dietary supplement to any distributor who is using or disseminating any advertisement or promotional material or making any oral statement that contains any representation prohibited by this Order, once Defendants know or should know that the distributor is or has been engaged in such conduct. Defendants shall immediately provide, by certified mail, all relevant information, including name, address, and telephone number of the distributor at issue, the nature of the violation, and any relevant materials used or disseminated, to the Regional Director, Federal Trade Commission, Southwest Region, 1999 Bryan Street, Suite 2150, Dallas, TX 75201. Attn: FTC v. Christopher Enterprises, Inc., et al. (D. Utah).

V. JUDGMENT

IT IS FURTHER ORDERED that judgment is hereby entered against Defendants

Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla, jointly and severally, in
the amount of ONE MILLION, FOUR HUNDRED THOUSAND DOLLARS (\$1,400,000.00),

provided, however, that upon the fulfillment of the payment obligations of

Paragraph VI of this Order, this judgment shall be suspended; and, <u>provided, further</u>, that this judgment shall be subject to the conditions set forth in Paragraph VII of this Order.

VI. MONETARY RELIEF

- A. **IT IS FURTHER ORDERED** that Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla shall be jointly and severally liable for payment of equitable monetary relief in the amount of ONE HUNDRED THOUSAND DOLLARS (\$100,000.00).
- B. Within ten (10) days of their execution of this Order, the Defendants shall transfer FIFTY THOUSAND DOLLARS (\$50,000.00) to their attorney, who shall hold it in escrow until the entry of this Order. Within ten (10) days of the date of entry of this Order, the Defendants' attorney shall transfer the escrowed amount in the form of a wire transfer to an account designated by the Commission or by certified or cashier's check made payable to the Federal Trade Commission, or such agent as the Commission may direct.
- C. Defendants shall pay the remaining FIFTY THOUSAND DOLLARS (\$50,000.00), in the form of wire transfers or certified or cashier's checks made payable to the Commission, or such agent as the Commission may direct, in four equal installments of TWELVE THOUSAND, FIVE HUNDRED DOLLARS (\$12,500.00), the first such payment to be made on the first day of the third month following the date of entry of this Order, and subsequent payments to be made on the first day of every third month thereafter, until all four payments are made.

- D. Time is of the essence for the payments specified above. In the event that Defendants do not fulfill, or only partially fulfill, the payment obligations set forth in this Paragraph, Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla shall be immediately liable for payment of the entire amount due, plus interest, less any payments already made.

 Notwithstanding any other provision of this Final Order, Defendants agree that, if they fail to meet the payment obligations set forth in this Paragraph, the facts as alleged in the Complaint in this action shall be taken as true in any subsequent litigation filed by the Commission to enforce its rights pursuant to this Order, including, but not limited to, a non-dischargeability complaint in any subsequent bankruptcy proceeding, and Defendants waive any right to contest any of the allegations set forth in the Complaint filed in this matter.
- E. All funds paid pursuant to this Order shall be deposited into a fund administered by the Commission or its agent to be used for equitable relief, including but not limited to consumer redress, and any attendant expenses for the administration of such equitable relief. In the event that direct redress to consumers is wholly or partially impracticable or funds remain after redress is completed, the Commission may apply any remaining funds for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to the Defendants' practices alleged in the Complaint. Any funds not used for such equitable relief and attendant expenses shall be deposited to the Treasury as disgorgement. Defendants shall have no right to challenge the Commission's choice of remedies under this Paragraph.
- F. Defendants shall have no right to contest the manner of distribution chosen by the Commission. No portion of any payments under the judgment herein shall be deemed a payment of

VII. RIGHT TO REOPEN WITH SUM CERTAIN

- A. IT IS FURTHER ORDERED that the Commission's agreement to and the Court's approval of this Order is expressly premised upon the truthfulness, accuracy, and completeness of the financial statements and information provided by Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla to the Commission on or about June 11, 2001, which contain material information relied upon by the Commission in negotiating and agreeing to the terms of this Order.
- B. If the Commission should have evidence that the above-referenced financial statements and information of any Defendant failed to disclose any material asset the value of which exceeds one thousand dollars (\$1,000), materially misrepresented the value of any asset, or made any other material misrepresentation or omission, the Commission may move that the Court reopen this Order for the sole purpose of allowing the Commission to modify the monetary liability of such Defendant. If the Court finds that any Defendant failed to disclose any material asset, materially misrepresented the value of any asset, or made any other material misrepresentation or omission in the above-referenced financial statements and information, the Court shall reinstate the judgment against such Defendant, in favor of the Commission, in the amount of ONE MILLION, FOUR HUNDRED THOUSAND DOLLARS (\$1,400,000.00), and the entire judgment shall become immediately due and payable, less any redress amounts previously paid. Should this judgment be modified as to the monetary liability of Defendants, this Order, in all other respects, shall remain in full force. Any proceedings instituted under this

Paragraph shall be in addition to and not in lieu of any other proceedings the Commission may initiate to enforce this Order. Solely for the purposes of reopening or enforcing this Paragraph, Defendants waive any right to contest any of the allegations set forth in the Complaint filed in this matter.

VIII. COLLECTING UNPAID REDRESS

IT IS FURTHER ORDERED that Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla shall cooperate fully with the Commission and its agents in all attempts to collect the amount due pursuant to Paragraphs V and VI if the Defendants fail to pay fully the amounts due at the times specified by this Order. In such event, Defendants agree to provide the Commission with their respective federal and state tax returns for the preceding three (3) years, and with full updated financial disclosures, in the form as was previously submitted as referenced in Paragraph VII, above, within ten (10) days of receiving a request from the Commission to do so. Defendants further authorize the Commission to verify all information provided on these disclosure forms with all appropriate third parties, including, but not limited to, financial institutions. The Defendants are hereby required, in accordance with 31 U.S.C. § 7701, to furnish the Commission social security numbers and/or employer identification numbers, which shall be used for purposes of collecting and reporting on any delinquent amount arising out of their relationship with the government.

IX. RECORD KEEPING

IT IS FURTHER ORDERED that Defendants Christopher Enterprises, Inc., Norman Bacalla, and Ruth Christopher Bacalla, for a period of five (5) years after the last date of dissemination of any representation covered by this Order, shall maintain and upon request make available to the Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession, custody, or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

X. DISTRIBUTION OF ORDER BY DEFENDANTS

IT IS FURTHER ORDERED that Defendants, for a period of five (5) years after the date of entry of this Order, shall deliver a copy of this Order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this Order, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. Defendants shall deliver this Order to current personnel within thirty (30) days after entry of this Order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Defendants shall maintain and, upon request, make available to the Commission for inspection and copying each such signed and dated statement for a period of five (5) years.

XI. NOTIFICATION

- A. IT IS FURTHER ORDERED that corporate Defendant Christopher Enterprises,
 Inc. shall notify the Commission at least thirty (30) days prior to any change in the corporation that may
 affect compliance obligations arising under this Order, including but not limited to a dissolution,
 assignment, sale, merger, or other action that would result in the emergence of a successor corporation;
 the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices
 subject to this Order; the proposed filing of a bankruptcy petition; or a change in the corporate name or
 address. Provided, however, that, with respect to any proposed change in the corporation about which
 Defendants learn less than thirty (30) days prior to the date such action is to take place, Defendants
 shall notify the Commission as soon as is practicable after obtaining such knowledge.
- B. **IT IS FURTHER ORDERED** that individual Defendants Norman Bacalla and Ruth Christopher Bacalla, within ten (10) days of entry of this Order, shall notify the Commission of (1) their residence address and mailing address; (2) their telephone number(s); (3) the name, address, and telephone number of their employers; (4) the full names of their employers' principals; (5) if applicable, the names of their supervisors; and (6) a description of their employers' activities, and the Defendants' duties and responsibilities.
- C. **IT IS FURTHER ORDERED** that individual Defendants Norman Bacalla and Ruth Christopher Bacalla, for a period of five (5) years after the date of entry of this Order, shall notify the Commission of any changes in their residence or mailing address or employment status. Notice of changes in employment status shall include: (1) the new employer's name, address and telephone number; (2) the full names of the employer's principals; (3) if applicable, the names of Defendant's

supervisors; and (4) a description of the employer's activities, and Defendant's duties and responsibilities.

XII. COMPLIANCE REPORT

IT IS FURTHER ORDERED that Defendants shall, within sixty (60) days after the date of entry of this Order, and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

XIII. MONITORING COMPLIANCE

IT IS FURTHER ORDERED that the Commission is authorized to monitor the compliance of Defendants with this Order by all lawful means, including but not limited to the following means:

- A. The Commission is authorized, without further leave of court, to obtain discovery from any person in the manner provided by Chapter V of the Federal Rules of Civil Procedure, Fed. R. Civ. P. 26-37, including but not limited to the use of compulsory process pursuant to Fed. R. Civ. P. 45, for the purpose of monitoring and investigating the compliance of Defendants with this Order.
- B. Nothing in this Order shall limit the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1, to investigate whether Defendants have violated any provision of this Order or Sections 5 or 12 of the FTC Act, 15 U.S.C. §§ 45 or 55.
 - C. For the purposes of the compliance reporting required by this Order and the monitoring

of compliance authorized by this Order, the Commission is authorized to communicate directly with each of the Defendants.

XIV. ACKNOWLEDGMENT OF RECEIPT OF ORDER

IT IS FURTHER ORDERED that within ten (10) days from the date of entry of this Order,

Defendants shall submit to the Commission a truthful sworn statement, in the form shown on Appendix

B, that shall acknowledge receipt of this Order.

XV. RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

SO ORDERED:	
DATED:	
	UNITED STATES DISTRICT JUDGE

SO STIPULATED:

WILLIAM E. KOVACIC General Counsel

JAMES R. GOLDER

JUDITH A. SHEPHERD

THOMAS B. CARTER Federal Trade Commission 1999 Bryan St., Suite 2150 Dallas, TX 75201 (214) 979-9376 (Golder) (214) 979-9383 (Shepherd) (214) 979-9372 (Carter) (214) 953-3079 (facsimile)

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Defendant

By Norman Bacalla, President

NORMAN BACALLA

Defendant

RUTH CHRISTOPHER BACALLA

Defendant

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