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6 Federal Trade Commission  
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8 Dallas, TX 75201-6803  
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10 214-979-9383 (Shepherd)  
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15 UNITED STATES DISTRICT COURT  
16 EASTERN DISTRICT OF CALIFORNIA

17	FEDERAL TRADE COMMISSION,	)	
18		)	
19	Plaintiff,	)	Civil Action No.
20		)	
21	v.	)	
22		)	
23	WESTERN BOTANICALS, INC.,	)	Stipulated Final Order for Permanent
24	a corporation, and	)	Injunction and Settlement of Claims
25		)	for Monetary Relief
26	RANDY C. GIBONEY and	)	
27	KYLE D. CHRISTENSEN,	)	
28	individually and as officers of the	)	
	corporation,	)	
		)	
	Defendants.	)	

27 Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), filed a Complaint  
28 for permanent injunction and other relief against Western Botanicals, Inc., Randy C. Giboney,

1 and Kyle D. Christensen, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC  
2 Act"), 15 U.S.C. § 53(b).

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

### 8 FINDINGS

9 1. This Court has jurisdiction over the subject matter of this case and jurisdiction  
10 over all parties. Venue in the Eastern District of California is proper.

11 2. The Complaint states a claim upon which relief can be granted, and the  
12 Commission has authority to seek the relief it has requested.

13 3. The activities of Defendants are in or affecting commerce, as defined in 15  
14 U.S.C. § 44.

15 4. Defendants waive all rights to seek judicial review or otherwise challenge or  
16 contest the validity of this Order. Defendants also waive any claim that they may have held  
17 under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this  
18 action to the date of this Order.

19 5. This action and the relief awarded herein are in addition to, and not in lieu of,  
20 other remedies as may be provided by law.

21 6. Each party shall bear its own costs and attorneys' fees.

22 7. Entry of this Order is in the public interest.

### 23 DEFINITIONS

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

25 1. "Competent and reliable scientific evidence" shall mean tests, analyses, research,  
26 studies, or other evidence based on the expertise of professionals in the relevant area, that have  
27 been conducted and evaluated in an objective manner by persons qualified to do so, using  
28 procedures generally accepted in the profession to yield accurate and reliable results.

1           2.       “Defendants” means Western Botanicals, Inc., Randy C. Giboney, and Kyle D.  
2 Christensen, and their successors, assigns, officers, agents, directors, servants, employees, and  
3 those persons in active concert or participation with them who receive actual notice of this Order  
4 by personal service or otherwise, whether acting directly or through any corporation, subsidiary,  
5 division, or other device.

6           3.       “Distributor” shall mean any purchaser or other transferee of any product covered  
7 by this Order who acquires such product directly or indirectly from Defendants with or without  
8 valuable consideration, and who sells, or who has sold, such product to other sellers or to  
9 consumers, including but not limited to individuals, retail stores, or catalogs.

10          4.       “Food” and “drug” shall mean “food” and “drug” as defined in Section 15 of the  
11 FTC Act, 15 U.S.C. § 55(b)-(c).

12          5.       “Comfrey product” shall mean any product consisting of, containing, or including  
13 as an ingredient any of the following plants, any part of the following plants, or any extract or  
14 derivative of the following plants: *Symphytum officinale* (also known as common comfrey),  
15 *Symphytum asperum* (also known as prickly comfrey), or *Symphytum x uplandicum* (also known  
16 as Russian comfrey).

17          6.       “Clearly and prominently” shall mean as follows:

18           a.       In an advertisement communicated through an electronic medium (such as  
19 television, video, radio, and interactive media such as the Internet, online services, and  
20 software), the disclosure shall be presented simultaneously in both the audio and visual  
21 portions of the advertisement. Provided, however, that in any advertisement presented  
22 solely through visual or audio means, the disclosure may be made through the same  
23 means in which the ad is presented. Provided, further, that in any advertisement  
24 communicated through interactive media which is presented predominantly through  
25 visual or audio means, the disclosure may be made through the same means in which the  
26 advertisement is predominantly presented. The audio disclosure shall be delivered in a  
27 volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The  
28 visual disclosure shall be of a size and shade, with a degree of contrast to the background

1 against which it appears, and shall appear on the screen for a duration and in a location  
2 sufficiently noticeable for an ordinary consumer to read and comprehend it. In addition to  
3 the foregoing, in interactive media, the disclosure shall also be unavoidable and shall be  
4 presented prior to the consumer incurring any financial obligation.

5 b. In a print advertisement, promotional material, or instructional manual, the  
6 disclosure shall be in a type size and location sufficiently noticeable for an ordinary  
7 consumer to read and comprehend it, in print that contrasts with the background against  
8 which it appears. In multi-page documents, the disclosure shall appear on the cover or  
9 first page.

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

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

23 7. A requirement that any Defendant communicate with the Commission shall mean  
24 that the Defendant shall send the necessary information via first-class mail, costs prepaid, to the  
25 Regional Director, Federal Trade Commission, Southwest Region, 1999 Bryan Street, Suite  
26 2150, Dallas, TX 75201. Attn: FTC v. Western Botanicals, Inc., et al. (E.D. Cal.).

27 8. The term “including” in this Order shall mean “without limitation.”

28 9. The terms “and” and “or” in this Order shall be construed conjunctively or

1 disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than  
2 exclusive.

3 **I. CONDUCT PROHIBITIONS**

4 A. **IT IS THEREFORE ORDERED** that, in connection with the manufacturing,  
5 labeling, advertising, promotion, offering for sale, sale, or distribution of any comfrey product,  
6 Defendants and their successors, assigns, officers, agents, directors, servants, employees, and  
7 those persons in active concert or participation with them who receive actual notice of this Order  
8 by personal service or otherwise, whether acting directly or through any corporation, subsidiary,  
9 division, or other device, are permanently restrained and enjoined:

- 10 1. From marketing such product for ingestion, for use as a suppository, or for  
11 external use on open wounds; and
- 12 2. From failing to make the following disclosure, clearly and prominently, in any  
13 advertisement, promotional material, package label, and package insert for any  
14 comfrey product marketed for other external use:

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

21 unless Defendants possess competent and reliable scientific evidence conclusively demonstrating  
22 that the product is free of pyrrolizidine alkaloids and safe for such uses. Provided, however  
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1 drug under any tentative final or final standard promulgated by the Food and Drug  
2 Administration or under any new drug application approved by the Food and Drug  
3 Administration.

### 4 **III. IDENTIFICATION OF PURCHASERS**

5 **IT IS FURTHER ORDERED** that Defendants shall:

6 A. Within seven (7) days after entry of this Order, deliver to the Commission a list, in  
7 the form of a sworn affidavit, of all distributors who purchased on or after January 1, 1998 a  
8 comfrey product, directly from Defendants or indirectly through one of Defendants' other  
9 distributors, to the extent that such distributor is known to Defendants through a diligent search  
10 of Defendants' records, including but not limited to computer files, sales records, and inventory  
11 lists. Such list shall include each distributor's name and address, and, if available, the  
12 distributor's telephone number and email address, and the full purchase price, including  
13 shipping, handling, and taxes, of the comfrey product(s) purchased from Defendants.

14 B. Within seven (7) days after entry of this Order, deliver to the Commission a list, in  
15 the form of a sworn affidavit, of all consumers who purchased on or after January 1, 1998 a  
16 comfrey product, directly from Defendants or indirectly through one of Defendants' distributors,  
17 to the extent that such consumer is known to Defendants through a diligent search of Defendants'  
18 records, including but not limited to computer files, sales records, and inventory lists. Such list  
19 shall include each consumer's name and address, and, if available, the consumer's telephone  
20 number and email address, and the full purchase price, including shipping, handling, and taxes,  
21 of the comfrey product(s) purchased from Defendants.

### 22 **IV. NOTIFICATION TO DISTRIBUTORS**

23 **IT IS FURTHER ORDERED** that:

24 A. Defendants shall not disseminate to any distributor any material containing any  
25 representation prohibited by this Order.

26 B. Defendants shall not, directly or indirectly, authorize any distributor to make any  
27 representation prohibited by this Order.

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1 C. Within thirty (30) days after entry of this Order, Defendants shall send by first  
2 class mail a notice, in the form shown on Appendix A, to each distributor with whom Defendants  
3 have done business since January 1, 1998, to the extent that such distributor is known to  
4 Defendants through a diligent search of Defendants' records, including but not limited to  
5 computer files, sales records, and inventory lists. The mailing shall not include any other  
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1 **V. MONETARY RELIEF**

2 **IT IS FURTHER ORDERED** that:

3 A. Judgment is hereby entered against Defendants in the amount of fifty thousand  
4 eight hundred dollars (\$50,800.00). Provided however, that this judgment shall be suspended  
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1 material asset, materially misrepresented the value of any asset, or made any other material  
2 misrepresentation or omission in the above-referenced financial statements and information, the  
3 Court shall enter judgment against Defendants, in favor of the Commission, in the amount of  
4 fifty thousand eight hundred dollars (\$50,800.00), which Defendants and the Commission  
5 stipulate is the amount of consumer injury caused by the Defendants. Should this judgment be  
6 modified as to the monetary liability of Defendants, this Order, in all other respects, shall remain  
7 in full force. Any proceedings instituted under this Section shall be in addition to and not in lieu  
8 of any other proceedings the Commission may initiate to enforce this Order. Solely for the  
9 purposes of reopening or enforcing this Section, Defendants waive any right to contest any of the  
10 allegations set forth in the Complaint filed in this matter.

11 **VII. RECORD KEEPING**

12 **IT IS FURTHER ORDERED** that Defendants, for a period of five (5) years after the  
13 last date of dissemination of any representation covered by this Order, shall maintain and upon  
14 request make available to the Commission for inspection and copying:

- 15 A. All advertisements and promotional materials containing the representation;
- 16 B. All materials that were relied upon in disseminating the representation; and
- 17 C. w (IT I FURTHER ORDu; abasainsseminating .0222 and ) Tj -36 -2eTinclusion prthis ma materj

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1 **X. COMPLIANCE REPORT**

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

6 **XI. MONITORING COMPLIANCE**

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

10 A. The Commission is authorized, without further leave of Court, to obtain discovery  
11 from any person in the manner provided by Chapter V of the Federal Rules of Civil Procedure,  
12 Fed. R. Civ. P. 26-37, including but not limited to the use of compulsory process pursuant to Fed.  
13 R. Civ. P. 45, for the purpose of monitoring and investigating the compliance of Defendants with  
14 this Order.

15 B. Nothing in this Order shall limit the Commission's lawful use of compulsory  
16 process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1, to investigate  
17 whether Defendants have violated any provision of this Order or Sections 5 or 12 of the FTC  
18 Act, 15 U.S.C. §§ 45 or 55.

19 C. For the purposes of the compliance reporting required by this Order and the  
20 monitoring of compliance authorized by this Order, the Commission is authorized to  
21 communicate directly with each of the Defendants.

22 **XII. ACKNOWLEDGMENT OF RECEIPT OF ORDER**

23 **IT IS FURTHER ORDERED** that within five (5) business days from the date of entry  
24 of this Order, Defendants shall submit to the Commission a truthful sworn statement, in the form  
25 shown on Appendix B, that shall acknowledge receipt of this Order.

26 **XIII. RETENTION OF JURISDICTION**

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

1 **SO STIPULATED:**

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214-953-3079 (facsimile)

Attorneys for Plaintiff  
FEDERAL TRADE COMMISSION

JOHN K. VINCENT  
United States Attorney

---

RANDY C. GIBONEY  
Defendant

---

KYLE D. CHRISTENSEN  
Defendant

---

WESTERN BOTANICALS, INC.  
Defendant  
By Randy C. Giboney, President

1 **APPENDIX A**

2 **FIRST CLASS MAIL**

3 [To be printed on Defendant's letterhead]

[date]

4 Dear [distributor's name]:

5  
6 This letter is to inform you that our company recently settled a civil dispute with the  
7 Federal Trade Commission regarding our advertising for certain products containing the herb  
8 comfrey, which the company has sold both directly to consumers and through resellers. As a part  
9 of the settlement, we must make sure that you comply with the settlement order, which was  
10 entered by the United States District Court for the Eastern District of California on \_\_\_\_\_  
11 \_\_\_\_\_ (date). Among other things, the settlement requires us to notify all purchasers of serious  
12 hazards that may attend use of comfrey if it is taken internally by oral ingestion, used as a  
13 suppository, or applied to broken skin, and to instruct resellers to stop using advertising or  
14 promotional materials that promote such uses of any product containing comfrey or that make  
15 any other representation prohibited by the settlement. Importantly, the settlement requires us to  
16 monitor our resellers and terminate all sales to any reseller who disseminates advertising or  
17 promotional materials that, expressly or by implication, make any claims about our comfrey  
18 products that we may not make pursuant to the order.

19 The FTC complaint alleged that the company engaged in deceptive advertising of its  
20 comfrey products, and the settlement imposes various requirements in connection with its past  
21 and future advertising of these and other products. According to the FTC complaint, our  
22 advertising materials claimed, expressly or by implication, that comfrey products may safely be  
23 used as oral preparations and may be applied to open wounds. The complaint challenges these  
24 claims as false and unsubstantiated. In particular, the FTC notes that comfrey contains  
25 pyrrolizidine alkaloids which have been linked to serious illness, occasionally leading to death.  
26 In addition, the complaint charged that the company made unsubstantiated claims that comfrey  
27 products are effective in preventing, treating, relieving, and curing certain illnesses and medical  
28 conditions.

The settlement prohibits us from making any of the challenged claims unless we have  
competent and reliable scientific evidence to support them. In addition, it prohibits us from  
marketing comfrey products for use internally, by ingestion, as a suppository, or applied to  
broken skin, and it requires us to make the following safety disclosure, clearly and prominently,  
in connection with the promotion and marketing of comfrey products:

**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>

The settlement with the FTC prohibits us from making unsubstantiated claims for any  
food, drug, dietary supplement, or health-related product or service. In addition, we are required  
to provide the FTC with purchaser information and to monitor and terminate all sales to resellers  
making prohibited claims for our comfrey products.

We request your assistance by asking you NOT to use, rely on, or distribute any  
advertising or promotional materials containing unsubstantiated claims and NOT to make  
unsubstantiated oral representations. If you have customers who buy the products for distribution  
or resale, please also notify them to do the same. If you or your customers continue to use  
prohibited materials or make false or unsubstantiated representations, we are required by the

1 settlement to stop doing business with you and to inform the FTC of your activities.

2 Although we do not admit that the FTC's allegations are true, we have agreed to send this  
3 letter as a part of our settlement with the FTC.

4 Please sign, date, and return this letter to [Defendant] at the above address,  
5 acknowledging your agreement to the terms set forth herein.

6 Thank you very much for your assistance,  
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9 [Defendant's signature]  
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14 **ACKNOWLEDGMENT AND AGREEMENT**

15 The undersigned acknowledges receipt of this letter and hereby agrees to its terms and  
16 conditions.

17 \_\_\_\_\_  
18 Date

19 \_\_\_\_\_  
20 Signature  
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1 **APPENDIX B**

2 UNITED STATES DISTRICT COURT  
3 EASTERN DISTRICT OF CALIFORNIA

4  
5 FEDERAL TRADE COMMISSION, )

6 Plaintiff, )

Civil Action No.

7 v. )

8 WESTERN BOTANICALS, INC., )

9 RANDY C. GIBONEY, and )

10 KYLE D. CHRISTENSEN, )

11 Defendants. )  
12

13 :

14 **AFFIDAVIT OF [DEFENDANT]**

15 [Defendant], being duly sworn, hereby states and affirms:

16 1. My name is \_\_\_\_\_. I am a citizen of the United States and am  
17 over the age of eighteen. I have personal knowledge of the matters discussed in this declaration,  
18 and if called as a witness, I could and would competently testify as to the matters stated herein. I  
19 am a defendant in the above captioned action.

20 2. On (date) \_\_\_\_\_  
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1 STATE OF \_\_\_\_\_

2 COUNTY OF \_\_\_\_\_

3 BEFORE ME this day personally appeared \_\_\_\_\_, who being first  
4 duly sworn, deposes and says that s/he has read and understands the foregoing statement and that  
5 s/he has executed the same for the purposes contained therein.

6 SUBSCRIBED AND SWORN TO before me this \_\_\_\_\_ day of \_\_\_\_\_, 200\_,  
7 by \_\_\_\_\_. S/he is personally known to me or has presented (state  
8 identification) \_\_\_\_\_ as identification.

9 \_\_\_\_\_  
10 Print Name

11 NOTARY PUBLIC,  
12 STATE OF \_\_\_\_\_

13 Commission Number  
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