

## APPENDIX A

### FIRST CLASS MAIL

[To be printed on Defendant's letterhead]

[date]

Dear [distributor's name]:

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

The FTC complaint alleged that the company engaged in deceptive advertising of its comfrey products, and the settlement imposes various requirements in connection with its past and future advertising of these and other products. According to the FTC complaint, our advertising materials claimed, expressly or by implication, that comfrey products may safely be used as oral preparations and suppositories and may be applied to open wounds. The complaint challenged these claims as false and unsubstantiated. In particular, the FTC notes that comfrey contains pyrrolizidine alkaloids which have been linked to serious illness, occasionally leading to death. In addition, the complaint charged that the company made unsubstantiated claims that comfrey products are effective in preventing, treating, relieving, and curing certain illnesses and medical 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, to monitor and terminate all sales to resellers making prohibited claims for our comfrey products, and to pay redress.

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

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

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

Thank you very much for your assistance,

[Defendant's signature]

#### **ACKNOWLEDGMENT AND AGREEMENT**

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## APPENDIX B

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Honorable Ted Stewart, United States District Judge for the District of Utah. A true and correct copy of the Order that I received is appended to this Affidavit.

I hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date) \_\_\_\_\_, at (city, state) \_\_\_\_\_, \_\_\_\_\_.

\_\_\_\_\_  
(Name of Defendant)

STATE OF \_\_\_\_\_

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

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

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

\_\_\_\_\_  
Print Name

NOTARY PUBLIC,  
STATE OF \_\_\_\_\_

Commission Number  
Affix Seal