

**Appendix Table. Consolidated Standards of Reporting Trials (CONSORT) Requirements for Controlled Trials of Herbal Interventions\***

Criteria	Black Cohosh: Single Herb Product	Multibotanical Product		
		Black Cohosh	Alfalfa	Boron Citrate
Latin binomial name	<i>Actaea racemosa</i>	<i>Actaea racemosa</i>	<i>Medicago sativa</i>	NA
Botanical authority				NA
Family name	Ranunculaceae	Ranunculaceae	Fabaceae	NA
Common names	Black bugbane, black snakeroot, bugwort, rattleroot, rattletop, rattleweed, macrotys	Black bugbane, black snakeroot, bugwort, rattleroot, rattletop, rattleweed, macrotys	Alfalfa, lucerne, purple medik, trefoil	Boron
Proprietary product name (i.e., brand name) or extract name; manufacturer	CimiPure (Naturex, Avignon, France)	†	†	†
Is product authorized (licensed, registered) in United States?	Yes, trademarked	No trademark or registration	No trademark or registration	No trademark or registration
Parts of plant used to produce the product or extract	Rhizome and root	Root	Leaf	NA
Type of product used (e.g., raw, fresh, or dry, extract), type and concentration of extraction solvent, ratio of herbal drug to extract	70% ethanol extract	Water and alcohol 4:1 extract	No solvents 4:1 extract	NA
Method of authentication of raw materials		GC	TLC	HPLC
Lot number of the raw material	M008250	SB01-0160	220100-50	021390910
State whether a voucher specimen (i.e., retention sample) retained; if so, where it is kept or deposited, and reference number	Yes, voucher specimen 51680, deposited at the New York Botanical Garden	No—past time of retention	No—past time of retention	No—past time of retention
Product dosage per capsule	80 mg	50 mg	100 mg	20 mg
Content (e.g., as weight, concentration; may be given as a range where appropriate) of all quantified herbal product constituents, both native and added, per dosage unit form	Per capsule: 80 mg of black cohosh, 510 mg of rice flour			
Added materials (binders, fillers, and other excipients)	Rice flour	None	None	None
Standardization	Triterpene glycosides	None	None	Boron
Product's chemical fingerprint and methods used	HPLC, CE	HPLC, CE	HP-TLC	HPLC, CE
For standardized products, quantity of active/marker constituents per dosage unit form	2.5%	NA	NA	NA
Amount detected	Triterpene glycosides, 3.125%	Triterpene glycosides, 4.4%	L-canavanine Alfalfa juice, 20% extract, 1 mg/g Alfalfa leaf, 4:1 extract, 3 mg/g	0.92 mg
Was a sample of the product (i.e., retention sample) retained? If so, where it is kept or deposited?	Yes			

\* All analyses were preformed by ConsumerLab.com. Specifics of special testing/purity testing are as follows (abbreviations used in tables defined at end of footnote): 1. Chlorinated pesticide screens were tested on the black cohosh and the multibotanical finished products, evaluated by GC/MS. The detection limit level was set at 50 parts per billion. The following were tested and were not found: pentachlorobenzene, tetrachloroaniline, hexachlorobenzene,  $\alpha$ -benzene hexachloride (BHC), pentachloronitrobenzene, lindane,  $\beta$ -BHC, heptachlor, pentachloroaniline,  $\delta$ -BHC, aldrin, pentachloroethoxyanisole, heptachlor, epoxide,  $\gamma$ -chlordane, endosulfan I,  $\alpha$ -chlordane, dieldrin, endrin, endrin aldehyde, endosulfan sulfate, dichloro-diphenyl-trichloroethane, dichlorodiphenyldichloroethylene, dichloro-diphenyl-dichloroethane, endosulfan II, methoxy-chlor, and endrine ketone. 2. Black cohosh, and the multibotanical were tested for heavy metals by inductively coupled plasma-mass spectroscopy. The black cohosh product contained  $<0.06 \mu\text{g}$  of lead,  $<0.06 \mu\text{g}$  of cadmium, and  $0.97 \mu\text{g}$  of arsenic. The multibotanical finished product contained  $<0.49 \mu\text{g}$  of lead,  $<0.0714 \mu\text{g}$  of cadmium, and  $1.16 \mu\text{g}$  of arsenic. 3. Alfalfa was tested for L-canavanine, an antinutrient, by using HP-TLC. The alfalfa leaf and juice extract raw material had 1 mg/g of L-canavanine in the juice extract (20% extract) and 3 mg/g in the leaf (4:1 extract). 4. Screening for estrogenic drug substances was detected by GC/MS. The following were tested and not found: diethylstilbestrol, estradiol, estrone, estriol, ethynyl estradiol, and tamoxifen. CE = capillary electrophoresis; GC = gas chromatography; HPLC = high-performance liquid chromatography; HP-TLC = high-performance thin-layer chromatography; MS = mass spectroscopy; NA = not available; TLC = thin-layer chromatography.

† Progyne (Progena, Albuquerque, NM, Lot 1051504).

‡ Per capsule: 50 mg of black cohosh, 100 mg of alfalfa, 1 mg of boron citrate, 50 mg of chaste tree, 100 mg of dong quai, 50 mg of false unicorn, 50 mg of licorice, 100 mg of oats, 100 mg of pomegranate, 100 mg of siberian ginseng; no filler or other constituents.

*Appendix Table—Continued*

**Multibotanical Product**

<b>Chaste Tree</b>	<b>Dong Quai</b>	<b>False Unicorn</b>	<b>Licorice</b>	<b>Oats Straw</b>	<b>Pomegranate</b>	<b>Siberian Ginseng</b>
<i>Vitex agnus-castus</i>	<i>Angelica sinensis</i>	<i>Chamaelirium luteum</i>	<i>Glycyrrhiza glabra</i>	<i>Avena sativa</i>	<i>Punica granatum</i>	<i>Eleutherococcus senticosus</i>
Verbenaceae	Apiaceae	Liliaceae	Fabaceae	Poaceae	Lythraceae	Araliaceae
Chaste berry, Monk's pepper, Abraham's balm, chaste lamb-tree, safe tree, Indian-spice, wild pepper	Dong quai, dang gui, tang-kuei	Starwort, helonias root, blazing star root, devil's bit, false unicorn	Lacrisse, sweet licorice, licorice root	Oats	Pomegranate	Ginseng
†	†	†	†	†	†	†
No trademark or registration	No trademark or registration	No trademark or registration	No trademark or registration	No trademark or registration	No trademark or registration	No trademark or registration
Berry	Root	Root	Root	Straw	Fruit	Root
Dry powder	Water and alcohol 4:1 extract	Water and alcohol 4:1 extract	Water and alcohol 4:1 extract	Water and alcohol 10:1 extract	Dry powder	Water and alcohol 0.8% extract
GC	GC	TLC	TLC	GC	GC	GC
38699C	SB01-0031	14C1-6	20012450	SB01-0136C-J	L5029P	SG001006C
No—past time of retention	No—past time of retention	No—past time of retention	No—past time of retention	No—past time of retention	No—past time of retention	No—past time of retention
50 mg	100 mg	50 mg	50 mg	100 mg	100 mg	100 mg
‡	‡	‡	‡	‡	‡	‡
None	None	None	None	None	None	None
None	None	None	None	None	None	Eleutherosides B and E
HPLC, CE	HPLC, CE	HPLC, CE	HPLC, CE	Not tested	HP-TLC	HPLC, CE
NA	NA	NA	NA	NA	NA	0.8%
Agnuside, 0.024%	Ligustilide, <0.001%; ferulic acid, 0.016%	Diosgenin (free) Not detected	Glycyrrhizic acid, 14%	Not tested	Polyphenolics Not detected	Eleutherosides B and E, 1.6%
Yes—for both products, a retention sample is being stored at the Group Health Center for Health Studies						