10.

28

1 2 3 4 5 6 IN THE UNITED STATES DISTRICT COURT 7 FOR THE NORTHERN DISTRICT OF CALIFORNIA 8 9 FEDERAL TRADE COMMISSION, No. C-08-00822 SI 10 Plaintiff, ORDER RE: FTC's PROPOSED PERMANENT INJUNCTION AND 11 OTHER EQUITABLE RELIEF v. 12 MEDLAB, INC., et al., 13 Defendants. 14 15 Now before the Court are defendants' objections to the equitable relief sought by the Federal 16 Trade Commission ("FTC"). On April 21, 2009, the Court granted the FTC's motion for summary 17 judgment against defendants for violations of sections 5(a) and 12 of the Federal Trade Commission 18 19 Act. Defendants have raised several objections to the FTC's proposed form of judgment ("Proposed 20 Order"). [Docket No. 49] The Court will consider each issue contested by defendants in turn. 21 22 "Covered Product" is limited to "weight-loss" products. 1. 23 The Proposed Order defines "Covered Product" as "any weight-loss product, dietary 24 25 supplement, food, drug or device." Defendants request that the definition of "Covered Product" be 26 amended as follows: 27

"Covered Product" to be defined as any product, dietary supplement, food,

drug, or device promoted as a weight-loss product."

Defendants contend this change is necessary to prevent the injunction from applying to any food, drug, or dietary supplement, or product promoted for *any* purpose. The Court agrees that the injunction should be narrowed. Therefore, "Covered Product" shall be defined as follows:

10. "Covered Product" shall mean any dietary supplement, food, drug, or device promoted for weight loss.

2. "Defendant Product" is limited to products marketed since January 1, 2005.

Plaintiff's Proposed Order defines "Defendant Product" as "any past, present, and future formulation of any dietary supplement marketed under the name Zyladex Plus, Questral Ac, Questral AC Fat Killer Plus, Rapid Loss 245, and Rapid Loss Rx." Defendants request that "Defendant Product" be limited to include only products marketed since January 1, 2005. Plaintiff does not oppose this modification. Therefore, the Order shall read:

7. "Defendant Product" shall mean any past, present, and future formulation of any dietary supplement marketed *since January 1, 2005* under the name Zyladex Plus, Questral AC, Questral AC Fat KillerPlus, Rapid Loss 245, and Rapid Loss Rx.

3. Prohibited representations are not limited to false or unsubstantiated claims.

Section I.A of the Proposed Order permanently restrains and enjoins defendants from making any claims that a Defendant Product or substantially similar product:

- 1. Causes permanent or long-term weight loss; or
- 2. Enables users to lose substantial weight or fat without the need to increase exercise or reduce caloric intake;

Section I.B of the Proposed Order permanently enjoins defendants from making or assisting in making any representation that Defendant Product or any other weight-loss product:

- 1. Causes weight loss or fat loss; or
- 2. Enables users to lose weight or fat, or any specific amount of weight or fat; unless the representation is true, non-misleading, and, at the time it is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

While Section I.A prevents defendants from repeating the claims about the products that were at issue in this case, section I.B applies more broadly to any weight-loss product. The latter provision requires defendants to have valid scientific evidence before making specified claims. Defendants wish to consolidate these sections so that defendants would be allowed to repeat the claims at issue in this case so long as they had scientific substantiation. As discussed in the Court's summary judgment order, defendants have made false scientific substantiation claims in the past. The relief requested by the FTC is necessary to prevent defendants from repeating these statements in the future. Therefore, defendants' proposed change is denied.

4. Section II covers any claim regarding the health benefits, performance, efficacy, safety, or side effects of any covered product.

Section II of plaintiff's Proposed Order applies to "Covered Products" and prohibits:

. . . any representation regarding the health benefits, performance, efficacy, safety, or side effects of any such product, unless the representation is true, non-misleading, and, at the time it is made, defendants posses and rely upon competent and reliable scientific evidence that substantiates the representation.

Defendants request that "any representation" be limited to cover only *material* representations. They also request that this section be limited to weight-loss products. Accordingly, defendants request section II be amended to read in pertinent part:

...any *material* representation regarding the health benefits, performance, efficacy, safety, or side effects of any weight-loss product

The Court rejects both of defendants' proposed changes. It is unnecessary to limit section II to "material" claims as all such representations are presumed to be material. See FTC v. Pantron I Corp., 33 F.3d 1088, 1095-96 (9th Cir. 1994). The "weight-loss" limitation is also unnecessary because in context, "such product" clearly refers to "Covered Product."

For the Northern District of California

5. "Devices" are included under Section IV's exemption provision.

Section IV of the Proposed Order provides a "safe harbor" provision for FDA-approved claims. As currently written, it does not explicitly apply to FDA-approved "devices." Defendants request that the final order provide an exemption for FDA-approved devices. The FTC does not oppose this modification. Accordingly, section IV.C shall be added as follows:

IV.C. Nothing in this Order shall prohibit defendants from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

6. Section IV.B shall not include "or any other law of the United States of America."

Section IV.B of plaintiff's Proposed Order states that defendants are not prohibited from making any representation:

B. For any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

Defendants seek to broaden section IV.B to include future laws enforced by the FDA. They request that section IV.B be amended as follows:

B. For any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 *or any other law of the United States of America*.

The Court agrees with plaintiff that the safe harbor should be narrow. Accordingly, the Court rejects defendants' proposed addition to section IV.B.

7. The monetary judgment shall not be modified.

This Court determined at summary judgment that individual defendant Holmes should be jointly and severally liable for the gross revenue received minus the amount already refunded to consumers, which amounts to \$2,694,253. Defendants request that the gross profit monetary judgment against

For the Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Holmes be limited to the net profits of the defendant companies. The Court rejected defendants' arguments on this issue in the summary judgment briefing; defendants have failed to raise any new issues that cause this Court to reconsider its ruling. Therefore, the monetary judgment shall not be changed.

Section VI.A shall not include defendants' requested "diligent search" qualification. 8.

As written, the customer list provision in section VI of the Proposed Order requires in relevant part that:

Defendants shall, within seven (7) days after service of this Order upon A. defendants, deliver to the Commission a list, in the form of a sworn affidavit, of all Eligible Purchasers.

Defendants seek to limit this requirement by including the following language:

A. Defendants shall, within seven (7) days after service of this Order upon Defendants, deliver to the Commission a list, to the extent that such purchasers are known to Respondents through a diligent search of their records, including but not limited to computer files, sales records, and inventory lists, in the form of a sworn affidavit. . . .

The FTC contends that defendants' proposed language may excuse defendants from providing records to which they are legally entitled yet not in possession of, thus hindering the FTC's ability to effectively provide consumer restitution. The Court agrees and rejects defendants' proposed change.

9. Section VI is limited to "Defendant Product."

Defendants request that they be required to produce only customer records pertaining to the ephedra-free pills at issue in this litigation. As discussed in Section 2 above, plaintiff does not oppose limiting the definition of "Defendant Product" to the ephedra-free pills marketed since January 1, 2005. Defendants' proposed change to section VI is therefore moot.

For the Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

10. Defendants proposed changes to in Sections VII through X are moot.

Defendants' proposed changes to Sections VII through X of the Proposed Order are moot in light of the Court's amendment to the definition of "Covered Product."

11. The record-keeping provisions shall extend for eight years.

The record-keeping provision outlined in Section IX of plaintiff's Proposed Order extends for eight years. Defendants request that the compliance period be limited to five years, which they claim would be consistent with other similar FTC actions. The FTC contends that the extended recordkeeping provision is necessary in order to evaluate defendants' ongoing compliance. The Court agrees with the FTC that the extended period is necessary in this case and rejects defendants' proposed change.

12. **Uncontested issues**

As defendants do not raise any further objections, all other provisions of the Proposed Order will be entered without change.

The FTC shall file a proposed order that incorporates the changes described herein.

IT IS SO ORDERED.

Dated: June 19, 2009

United States District Judge