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UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

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UNITED STATES OF AMERICA, Plaintiff,)))	
v. BAYER CORPORATION,)) CIV. ACTION NO.	07-01 (HAA)
Defendant)))	

CONSENT DECREE

WHEREAS: Plaintiff, the United States of America, has commenced this action by filing the Complaint herein; defendant, Bayer Corporation, has waived service of the Summons and Complaint; the parties have been represented by the attorneys whose names appear hereafter; defendant does not admit that it has violated the law as alleged in the complaint or that the facts as alleged in the complaint, other than the jurisdictional facts, are true; and the parties have agreed to settlement of this action upon the following terms and conditions, without adjudication of the merits of any issue of fact or law;

THEREFORE, on the joint motion of plaintiff and defendant, it is hereby ORDERED and DECREED as follows:

- 1. This Court has jurisdiction over the subject matter and the parties.
- 2. The Complaint states a claim upon which relief may be granted against defendant under Sections 5(1), 13(b) and 16(a) of the Federal Trade Commission Act ("FTC Act"), 15

 U.S.C. §§ 45(1), 53(b) and 56(a).

DEFINITIONS

- "Bayer Corporation" means Bayer Corporation and all of its divisions and subsidiaries, including, but not limited to, Bayer Healthcare, LLC;
- "Commerce" means as defined in Section 4 of the Federal Trade Commission Act, 15
 U.S.C. § 44;
- 3. "Competent and reliable scientific evidence" means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has 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.
- 4. "FTC" or "Commission" means the Federal Trade Commission.
- 5. "FTC Order" means the FTC Order in FTC Docket No. C-3323, a copy of which is attached hereto as Exhibit A and made part of this Consent Decree.
- 6. "Person" means a natural person, organization or other legal entity, including a partnership, corporation, proprietorship, association, cooperative, or any other group acting together as an entity.
- 7. "Weight control product" means any dictary supplement or food product or program designed or used to prevent weight gain, or to produce weight loss, reduction or elimination of fat, slimming, or caloric deficit, in a user of the product or program.

- 8. The terms "and" and "or" in this Consent Decree shall be construed conjunctively or disjunctively, as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.
- 9. The term "including" in this Consent Decree means "including, without limitation."

I.

CIVIL PENALTY

IT IS FURTHER ORDERED that:

- A. Pursuant to Section 5(1) of the FTC Act, 15 U.S.C. § 45(1), defendant Bayer

 Corporation, and its successors and assigns, shall pay a monetary civil penalty of
 three million, two hundred thousand dollars (\$3,200,000);
- B. Defendant, and its successors and assigns, shall make the payment required by Subpart A of this Part within five (5) days after the date of entry of this Consent Decree by electronic fund transfer in accordance with the instructions provided by: The Office of Consumer Litigation, Civil Division, U.S. Department of Justice, Washington, D.C. 20530; and
- C. In the event of any default in payment, which default continues for ten (10) days beyond the due date of payment, the entire unpaid penalty, together with interest as computed pursuant to 28 U.S.C. § 1961 from the date of default to the date of payment, immediately will become due and payable.

II.

PROHIBITION AGAINST VIOLATING FTC ORDER

IT IS FURTHER ORDERED that defendant Bayer Corporation, and its successors and assigns, and their officers, agents, representatives, and employees, and all persons in active concert or participation with any one or more of them who receive actual notice of this Consent

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Decree by personal service or otherwise, are hereby permanently enjoined from ever violating, directly or through any corporation, subsidiary, division, or other device, any provision of the FTC Order; *provided, however*, that, in the event that the FTC Order is hereafter modified, defendant's compliance with such Order as so modified will not be deemed a violation of this Part.

Ш.

PROHIBITED UNSUBSTANTIATED REPRESENTATIONS

IT IS FURTHER ORDERED that defendant Bayer Corporation, and its successors and assigns, and their officers, agents, representatives, and employees, and all persons in active concert or participation with any one or more of them who receive actual notice of this Consent Decree by personal service or otherwise, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any dietary supplement, multivitamin, including but not limited to One-A-Day WeightSmart, or weight-control product, in or affecting commerce, are hereby permanently enjoined from making any representation, including through endorsements or trade name, expressly or by implication:

- A. That such product or any of its ingredients:
 - 1. Increases metabolism;
 - Enhances metabolism through its EGCG content;
 - Helps prevent some of the weight gain associated with a decline in metabolism in users over age 30;
 - 4. Helps users control their weight by enhancing their metabolism;
 - Makes a material contribution to any program or system that promotes weight maintenance;

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- 6. Can or will cure, treat, or prevent any disease; or
- 7. Have any effect on the structure or function of the human body; or
- В. About the benefits, performance, efficacy, safety or side effects, of such product or any of its ingredients;

unless at the time the representation is made, defendant Bayer Corporation possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

JV.

FOOD AND DRUG ADMINISTRATION

IT IS FURTHER ORDERED that nothing in this Consent Decree prohibits defendant Bayer Corporation from making:

- Α. 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; and
- В. Any representation 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.

V.

Document 2

DISTRIBUTION OF CONSENT DECREE BY DEFENDANT

IT IS FURTHER ORDERED that, for a period of five (5) years from the date of entry of this Consent Decree, defendant Bayer Corporation, and its successors and assigns, shall:

- Λ. Provide a copy of the Consent Decree and FTC Order to, and obtain a signed and dated acknowledgment of receipt from; each officer and director; and all personnel, whether such persons are designated as employees, consultants, independent contractors or otherwise, having supervisory responsibilities with respect to the advertising or promotion of any product or program covered by this Consent Decree. A copy of the Consent Decree and FTC Order shall be delivered to current personnel within thirty (30) days after the date of entry of the Consent Decree, and to future personnel within thirty (30) days after the person assumes such position or responsibilities, and
- В. Maintain, for a period of three (3) years after creation, and upon request, make available to representatives of the Commission, the original signed and dated acknowledgments required in Subpart A of this Part.

VI.

RECORD-KEEPING PROVISIONS

IT IS FURTHER ORDERED that, for a period of five (5) years from the date of entry of this Consent Decree, defendant Bayer Corporation, and its successors and assigns, shall maintain and, upon request, make available to the Commission, copies of all business records demonstrating compliance with the terms and provisions of this Consent Decree, including but not limited to:

- Α. Accounting records that reflect the cost of products and programs sold, revenues generated and the disbursement of such revenues;
- В. Personnel records accurately reflecting the name, address, and telephone number of each officer and director; and all personnel, whether such persons are designated as employees, consultants, independent contractors or otherwise. having supervisory responsibilities with respect to the advertising or promotion of any product or program covered by this Consent Decree; that person's job title or position; the date upon which the person commenced work; and the date and reason for the person's termination, if applicable;
- C. A copy of each advertisement containing any representation covered by this Consent Decree, including a videotape of any television advertisement and an audiotape of any radio advertisement;
- D. All materials that were relied upon in disseminating such representation; and
- E. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VII.

COMPLIANCE REPORTING BY DEFENDANT

IT IS FURTHER ORDERED that:

Λ. For a period of ten (10) years from the date of entry of this Consent Decree. defendant Bayer Corporation, and its successors and assigns, shall notify the Commission of any changes in corporate structure that may affect compliance obligations arising out of this Consent Decree, including but not limited to,

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 the acts or practices subject to this Consent Decree, the filing of a bankruptcy petition, or change in the corporate name or address, at least thirty (30) days prior to the effective date of any proposed change; provided that, with respect to any proposed change in a corporation about which defendant learns less than thirty (30) days prior to the date such action is to take place, defendant shall notify the Commission as soon as is practicable after obtaining such knowledge;

- В. Within thirty (30) days after receipt of a written request by a representative of the Commission, defendant Bayer Corporation, and its successors and assigns, shall submit written reports (under oath, if requested) and produce documents with respect to any conduct subject to this Consent Decree; and
- C. Defendant Bayer Corporation shall, in accordance with 31 U.S.C. § 7701, furnish to the Commission its taxpayer identifying number (employer identification number), which will be used for purposes of collecting and reporting on any delinquent amount arising out of defendant's relationship with the government.

VIII.

WRITTEN NOTIFICATIONS BY DEFENDANT

IT IS FURTHER ORDERED that, for the purposes of this Consent Decree, defendant Bayer Corporation shall, unless otherwise directed by the Commission or its representatives, mail all written notifications to the Commission or the Commission's Associate Director for Enforcement to:

Associate Director for Enforcement

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Federal Trade Commission 600 Pennsylvania Avenue, N.W. Washington, D.C. 20580 Re: U.S. v. Bayer Corporation (Miles, Inc.)

IX.

CONTINUING JURISDICTION

IT IS FURTHER ORDERED that this Court will retain jurisdiction of this matter for the purpose of enabling any of the parties to the Consent Decree to apply to the Court at any time for such further orders or directives as may be necessary or appropriate for the interpretation or modification of this Consent Decree, for the enforcement of compliance therewith, for the redress of any violations thereof, or for the punishment of any violations thereof.

X.

SCOPE OF CONSENT DECREE

IT IS FURTHER ORDERED that:

- A. Except with regard to its enforcement by the United States, this Consent Decree does not constitute evidence of any liability, wrongdoing, or fault by defendant Bayer Corporation, and it shall not have any preclusive effect on any claim or defense of any person or entity in any pending or future legal or administrative proceeding or action; and
- B. This Consent Decree resolves only claims against the named defendant and does not preclude the United States from initiating further action or seeking any remedy against any other persons or entities, including without limitation persons or entities who may be subject to portions of this Consent Decree by virtue of actions taken in concert or participation with defendant, and persons or entities in any type of indemnification or contractual relationship with defendant.

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SO ORDERED.

APPROVED this 31ch

of June, 20

United States District Judge

The parties, by their respective counsel, hereby consent to the terms and conditions of the Consent Decree as set forth above and consent to the entry thereof. Defendant waives any rights that may arise under the Equal Access to Justice Act, 28 U.S.C. § 2412, amended by Pub. L. 104-21, 110 Stat. 847, 863-64 (1996).

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By:

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