WILLARD K. TOM
General Counsel

THEODORE H. HOPPOCK
DEVIN W. DOMOND
ELISE D. WHANG
SYDNEY KNIGHT
Federal Trade Commission
600 Pennsylvania Avenue
Room NJ-3212
Washington, DC 20580
202-326-3087
202-326-3529 (facsimile)

ATTORNEYS FOR PLAINTIFF
FEDERAL TRADE COMMISSION

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, Plaintiff, v. **IOVATE HEALTH SCIENCES USA, INC.**, et al., Defendants.	**CASE NO.**

STIPULATED FINAL JUDGMENT AND ORDER FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed a Complaint for Permanent Injunction and Other Equitable Relief against corporations, Iovate Health Sciences USA, Inc., Iovate Health Sciences, Inc., and Iovate Health Sciences Group, Inc., n/k/a Kerr Investment Holding Corp., pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), alleging deceptive acts or practices and false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

The Commission and Defendants have stipulated to the entry of this Order in settlement of the Commission's allegations against Defendants. The Court, having been presented with this Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief ("Order"), finds as follows:

FINDINGS

1. This Court has jurisdiction over the subject matter of this case and, pursuant to the Stipulation in Paragraph 4 below, jurisdiction over all parties. Venue in the United States District Court for the Western District of New York is proper.

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

3. The activities of Defendants, for purposes of this Order, are in or affecting commerce, as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

4. The Commission and Defendants stipulate and agree to entry of this Order under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), without trial or final adjudication of any issue of fact or law. By entering into this stipulation, Defendants do not admit or deny any of the allegations set forth in the Complaint, other than jurisdictional facts, to which Defendants are stipulating only as to this action and subsequent actions arising from this action, including enforcement and modification of this Order.

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

6. This action and the relief awarded herein are in addition to, and not in lieu of,

Inc., and Iovate Health Sciences Group, Inc., n/k/a Kerr Investment Holding Corp., and their successors and assigns.

2. "Iovate Products" means, collectively, Cold MD, Germ MD EZ-Swallow Rapid-Tabs, Germ MD Effervescent Tablets, Allergy MD, Allergy MD Rapid-Tabs, nanoSLIM, and Accelis.

3. "Commerce" means as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

4. "Adequate and well-controlled human clinical study" means a human clinical study that is randomized, double-blind, placebo-controlled, and conducted by persons qualified by training and experience to conduct such study.

5. "Covered Product" means any dietary supplement, food, or drug, including, but not limited to, the Iovate Products.

6. "Essentially Equivalent Product" means a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the covered product; provided that the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field demonstrates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

7. "Endorsement" means as defined in 16 C.F.R. § 255.0(b).

8. "Food" and "drug" means as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

9. "Dietary supplement" means:

a. any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or

b. any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

10. The term "including" in this Order means "including without limitation."

11. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

PROHIBITED REPRESENTATIONS: DISEASE CLAIMS

IT IS HEREBY ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any drug or dietary supplement, in or affecting commerce, are hereby permanently restrained and enjoined from making, or assisting others in making, directly or by implication, including

through the use of a product name, endorsement, depiction, or illustration, any representation that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that such product:

A. Reduces the risk, incidence, or frequency of colds or flu;

B. Prevents colds or flu;

C. Protects against colds or flu in crowded places;

D. Reduces the severity or duration of colds or flu;

E. Provides relief from hay fever; or

F. Provides relief (including fast or long-lasting relief) from seasonal, all-season, or environmental allergies;

unless the representation is non-misleading and such product: is subject to a final OTC drug monograph promulgated by the Food and Drug Administration (FDA) for such use, and conforms to the conditions of such use; remains covered by a tentative final OTC drug monograph for such use, and adopts the conditions of such use; or is the subject of a new drug application for such use approved by FDA, and conforms to the conditions of such use.

II.

PROHIBITED REPRESENTATIONS: WEIGHT-LOSS CLAIMS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, are hereby permanently restrained and

enjoined from making, or assisting others in making, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation that such product:

A. Causes weight loss; or

B. Causes rapid weight loss;

unless the representation is non-misleading and, at the time of making such representation, Defendants possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Section, competent and reliable scientific evidence shall consist of at least two adequate and well-controlled human clinical studies of the Covered Product, or of an Essentially Equivalent Product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true. Defendants shall have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III.

PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, are hereby permanently restrained and enjoined from making, or assisting others in making, directly or by implication, including

through the use of a product name, endorsement, depiction, or illustration, any representation, other than representations covered under Sections I or II of this Order, about the health benefits, performance, or efficacy of any Covered Product, other than claims regarding bodybuilding and exercise performance (e.g., increased muscle mass or body mass, increased strength and power, improved weight training performance, increased work-out intensity, improved muscle endurance, or improved muscle recovery), unless the representation is non-misleading, and, at the time of making such representation, Defendants possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Section, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

IV.

PROHIBITED REPRESENTATIONS REGARDING TESTS OR STUDIES

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, are hereby permanently restrained and enjoined from misrepresenting, in any manner, expressly or by implication, including through the use of any product name or endorsement, the existence, contents, validity, results,

conclusions, or interpretations of any test or study, in connection with any representations covered by Sections I through III of this Order.

V.

PROHIBITED REPRESENTATIONS REGARDING HOMEOPATHIC DRUGS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, are hereby permanently restrained and enjoined from making, or assisting others in making, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation that such product is a homeopathic drug unless:

A. Such product is recognized as such by the Homeopathic Pharmacopoeia of the United States; and

B. The representation is true and not misleading.

VI.

FDA APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order shall prohibit Defendants from making 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.

VII.

the Commission. No portion of any payment under the judgment herein shall be deemed a payment of any fine, penalty, or punitive assessment.

D. Defendants relinquish all dominion, control, and title to the funds paid to the fullest extent permitted by law. Defendants shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise.

E. Defendants agree that the facts as alleged in the Complaint filed in this action shall be taken as true without further proof in any bankruptcy case or subsequent civil litigation pursued by the Commission to enforce its rights to any payment or money judgment pursuant to this Order, including, but not limited to, a nondischargeability complaint in any bankruptcy case. Defendants further stipulate and agree that the facts alleged in the Complaint establish all elements necessary to sustain an action pursuant to, and that this Order shall have collateral estoppel effect for purposes of, Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S. C. § 523(a)(2)(A). For all other purposes and with respect to all other parties, Defendants' stipulation in this Section shall have no effect. It is specifically agreed and acknowledged that this Section is not intended to be, nor shall it be, construed as an admission of liability by Defendants with respect to the allegations set forth in the Complaint with respect to any claims or demands by any third parties.

F. In accordance with 31 U.S.C. § 7701, Defendants are hereby required, unless they have done so already, to furnish to the Commission their taxpayer identifying numbers, which shall be used for the purposes of collecting and reporting on any delinquent amount arising out of Defendants' relationship with the government.

G. Proceedings instituted under this Part are in addition to, and not in lieu of, any other civil or criminal remedies that may be provided by law, including any other proceedings the Commission may initiate to enforce this Order.

VIII.

COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring and investigating compliance with any provision of this Order.

A. Within ten (10) days of receipt of written notice from a representative of the Commission, Defendants shall submit additional written reports, which are true and accurate and sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and provide entry during normal business hours to any business location in Defendants' possession or direct or indirect control to inspect the business operation;

B. In addition, the Commission is authorized to use all other lawful means, including, but not limited to:

1. obtaining discovery from any person, without further leave of court, using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36, 45 and 69; and

2. having its representatives pose as consumers and suppliers to Defendants, their employees, or any other entity managed or controlled in whole or in part by Defendants, without the necessity of identification or prior notice; and

C. Defendants shall permit representatives of the Commission to interview any employer, consultant, independent contractor, representative, agent, or employee who has agreed to such an interview, relating in any way to any conduct subject to this Order. The person interviewed may have counsel present.

Provided however, that nothing in this Order shall limit the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).

IX.

COMPLIANCE REPORTING

IT IS FURTHER ORDERED that, in order that compliance with the provisions of this Order may be monitored:

A. For a period of three (3) years from the date of entry of this Order, Defendants shall notify the Commission in writing of any changes in the corporate structure of Defendants or any business entity that a Defendant directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this Order, including, but not limited to: incorporation or other organization; a dissolution, assignment, sale, merger, or other

manner and form in which they have complied and are complying with this Order. This report shall include, but not be limited to:

1. A copy of each acknowledgment of receipt of this Order, obtained pursuant to the Section titled “Distribution of Order”; and

X.

RECORD KEEPING PROVISIONS

IT IS FURTHER ORDERED that, for a period of six (6) years from the date of entry of this Order, Defendants and any business of which any Defendant is a majority owner or

promotion, offering for sale, sale, or distribution, of products covered by Sections I through III of this Order;

F. All materials that were relied upon in making any representations contained in the materials identified in Subparagraph 5 above, including all documents evidencing or referring to the accuracy of any claim therein or to the benefits, performance, or efficacy of any products covered by Sections I through III of this Order, including, but not limited to, all tests, reports, studies, demonstrations, or other evidence that confirms, contradicts, qualifies, or calls into question the accuracy of any claim regarding the benefits, performance, or efficacy of any products covered by Sections I through III of this Order, including complaints and other communications with consumers or with governmental or consumer protection agencies;

G. Records accurately reflecting the name, address, and telephone number of each manufacturer or laboratory engaged in the development or creation of any testing obtained for the purpose of manufacturing, labeling, advertising, marketing, promoting, offering for sale, selling, or distributing any products covered by Sections I through III of this Order;

H. Copies of all contracts concerning the manufacturing, labeling, advertising, marketing, promotion, offering for sale, sale, or distribution of any products covered by Sections I through III of this Order; and

I. All records and documents necessary to demonstrate full compliance with each provision of this Order, including, but not limited to, copies of acknowledgments of receipt of this Order required by the Sections titled “Distribution of Order” and “Acknowledgment of

Receipt of Order" and all reports submitted to the FTC pursuant to the Section titled "Compliance Reporting."

XI.

DISTRIBUTION OF ORDER

IT IS FURTHER ORDERED that, for a period of three (3) years from the date of entry of this Order, Defendants shall deliver copies of the Order as directed below:

A. Defendants shall deliver a copy of this Order to: (1) each of its principals, officers, directors, and managers; (2) all of its employees, agents, and representatives who engage in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure set forth in Subsection A of the Section titled "Compliance Reporting." For current personnel, delivery shall be within five (5) days of service of this Order upon Defendant. For new personnel, delivery shall occur prior to their assuming their responsibilities. For any business entity resulting from any change in structure set forth in Subsection A of the Section titled "Compliance Reporting," delivery shall be at least ten (10) days prior to the change in structure.

B. Defendants shall secure a signed and dated statement acknowledging receipt of the Order, within thirty (30) days of delivery, from all persons receiving a copy of the Order pursuant to this Section.

XII.

ACKNOWLEDGMENT OF RECEIPT OF ORDER

IT IS FURTHER ORDERED that Defendants, within five (5) business days of receipt of this Order as entered by the Court, shall submit to the Commission a truthful sworn statement acknowledging receipt of this Order.

XIII.

RETENTION OF JURISDICTION

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

SO ORDERED:

Dated: _____

_____
UNITED STATES DISTRICT JUDGE