UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, Plaintiff, v. CHEMBIO DIAGNOSTIC SYSTEMS, INC., Defendant.	Case No. **STIPULATED FINAL ORDER FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF**

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), filed a complaint for permanent injunction and other equitable relief, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), stating that defendant Chembio Diagnostic Systems, Inc. allegedly engaged in deceptive acts or practices and false advertising in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

The Commission and defendant have stipulated to the entry of this Stipulated Final Order for Permanent Injunction and Other Equitable Relief ("Order") in settlement of the Commission's complaint against defendant. The Court, being advised in the premises, finds as follows:

FINDINGS

1. In its complaint, the Commission alleged that defendant violated Sections 5(a) and 12 of the FTC Act, 15 U.S.C. § § 45(a) and 52. The Commission sought permanent injunctive relief for alleged deceptive acts or practices by defendant in connection with the marketing and sale of tests that defendant represented may be used to detect the human immunodeficiency virus in human blood.

2. The Commission has the authority under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to seek the relief it has requested.

3. This Court has jurisdiction over the subject matter of this case, and jurisdiction over defendant. Venue in the Eastern District of New York is proper, and the complaint states a claim upon which relief can be granted against the defendant under Sections 5(a), 12, and 13(b) of the FTC Act, 15 U.S.C. §§ 45(a), 52, and 53(b).

4. The activities of defendant as alleged in the Commission's complaint were or are in or affecting commerce, as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

5. The Commission and the defendant stipulate and agree to this Order, without trial or final adjudication of any issue of fact or law, to settle and resolve all matters in dispute arising from the complaint to the date of entry of this Order. By entering this stipulation, defendant does not admit any of the allegations set forth in the complaint, other than jurisdictional facts.

6. Defendant waives all rights to seek judicial review or otherwise challenge or contest the validity of this Order. Defendant also waives any claim that it 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. Each party to this Order shall bear its own costs and attorneys' fees incurred in connection with this action.

7. Entry of this Order is in the public interest.

8. Pursuant to Federal Rule of Civil Procedure 65(d), the provisions of this Order are binding upon defendant, and its officers, agents, servants, employees, attorneys and all other persons or entities in active concert or participation with it, who receive actual notice of this Order by personal service or otherwise.

ORDER

I. DEFINITIONS

IT IS THEREFORE STIPULATED AND ORDERED that for the purposes of this Order, the following definitions shall apply:

A. "Defendant" shall mean Chembio Diagnostics, Inc. ("Chembio"), its divisions and subsidiaries, and its successors or assigns.

B. "Haendler" shall mean Tomas Haendler, the President of Chembio.

C. "Participating associates" shall refer to defendant's officers, agents, servants, employees, and all those persons or entities in active concert or participation with defendant who receive actual notice of this Order by personal service or otherwise.

D. "Human immunodeficiency virus" ("HIV") shall refer to all types or strains of the virus that causes acquired immunodeficiency syndrome ("AIDS"), an infectious disease characterized by immune system failure.

E. "HIV test" shall refer to any product that is advertised, marketed, promoted,

offered for sale, distributed or sold with express or implied representations that the product will or may detect the presence of HIV in any human, including but not limited to the "HIV 1 / 2 STAT-PAK Ultra Fast" test and any other substantially similar product.

F. "Device" shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions in humans.

G. "Approved by the U.S. Food and Drug Administration ("FDA") means any HIV test or other device that can be sold, distributed or delivered within the United States pursuant to the Federal Food, Drug and Cosmetic Act ("FFD&C Act"); ***or*** an HIV test or other device that has been approved for market by the FDA through either: (1) Premarket Approval; or (2) Completion of a Product Development Protocol; ***or*** an HIV test or other device that has been cleared for market by the FDA through either (1) the clearance of a Premarket Notification ("510(k) notice"), or (2) by an exemption from the Premarket Notification or clearance requirements of the FFD&C Act.

H. "Unapproved HIV test" shall mean any HIV test that is not approved by the FDA.

I. "Unapproved device" shall mean any device that is not approved by the FDA.

J. "Competent and reliable scientific evidence" means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant

area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the professions to yield accurate and reliable results.

K. "Document(s)" or "record(s)" shall refer to

1. The original or a true copy of any written, typed, printed, electronically stored, transcribed, taped, recorded, filmed, punched, or graphic matter or other data compilations of any kind, including, but not limited to, letters, e-mail or other correspondence, messages, memoranda, interoffice communications, notes, reports, summaries, manuals, magnetic tapes or discs, tabulations, books, records, checks, invoices, work papers, journals, ledgers, statements, returns, reports, schedules, or files; and

2. Any information stored on any desktop personal computer ("PC") and workstations, laptops, notebooks, and other portable computers, whether assigned to individuals or in pools of computers available for shared use; and home computers used for work-related purposes; backup disks and tapes, archive disks and tapes, and other forms of offline storage, whether stored onsite with the computer used to generate them, stored offsite in another company facility or stored offsite by a third-party, such as in a disaster recovery center; and computers and related offline storage used by defendant's participating associates, which may include persons who are not employees of the company or who do not work on company premises.

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

M. The term "including" shall mean "without limitation."

N. Any requirement that defendant "notify" or "provide" any information or material to the Commission, shall mean that defendant shall send the necessary information or material via first-class mail, costs prepaid, to:

Associate Director for Advertising Practices
Federal Trade Commission
600 Pennsylvania Ave., N.W., Room S-4002
Washington, DC 20580
Attn: FTC v. Chembio Diagnostic Systems, Inc., Matter No. 9923269

II. PROHIBITED BUSINESS ACTIVITIES

IT IS FURTHER STIPULATED AND ORDERED that defendant and its participating associates, directly or indirectly, or acting through any corporation, entity or person under its control, are permanently enjoined from:

A. Making, or assisting others in making, directly or by implication, any material false or misleading oral or written statement or representation in connection with the advertising, marketing, promotion, offer for sale, distribution, or sale of any unapproved HIV test or other unapproved device, including misrepresenting, in any manner, directly or by implication, the accuracy or efficacy of any unapproved HIV test or other unapproved device;

B. Making, or assisting others in making, any representation, in any manner, directly

or by implication, regarding the accuracy or efficacy of any unapproved HIV test or other unapproved device, including any implied representation that such device is fit for its intended use, unless, at the time of making such representation, defendant possesses and relies upon competent and reliable scientific evidence that substantiates the representation;

C. Misrepresenting, in any manner, directly or by implication, that the FDA or any other local, state, regional, national or international government or public health organization has reviewed, evaluated, is affiliated with, or otherwise endorses or supports, any unapproved HIV test or other unapproved device; and

D. Misrepresenting, in any manner, directly or by implication, any other fact material to a customer's decision to purchase any unapproved HIV test or other unapproved device.

III. PRESERVATION OF RECORDS

IT IS FURTHER STIPULATED AND ORDERED that, for a period of five (5) years from the date of entry of this Order, defendant and its participating associates are enjoined from failing to create and from failing to retain for a period of three (3) years following the date of such creation, unless otherwise specified:

A. All documents, kept in the regular course of business, evidencing or referring to the accuracy or efficacy of any unapproved HIV test or other unapproved device advertised, marketed, promoted, offered for sale, distributed or sold by defendant, including, but not limited to, all tests, reports, studies, demonstrations, or other

evidence that confirm, contradict, qualify, or call into question the accuracy or efficacy of such device;

B. Books, records and accounts, kept in the regular course of business, that, in reasonable detail, accurately and fairly reflect the cost of unapproved HIV tests or other unapproved devices, and revenues generated from such tests;

C. Records accurately reflecting: the name, address, and telephone number of each person employed by defendant, including as an independent contractor, who is engaged in the advertising, marketing, promotion, offer for sale, distribution, or sale of any unapproved HIV test or other unapproved device; 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;

D. Records, kept in the regular course of business, containing the names, addresses, telephone numbers, dollar amounts paid, quantity of items or services purchased, and description of items or services purchased, for all purchasers to whom defendant has sold, invoiced or shipped any unapproved HIV test or other unapproved device;

E. Records that reflect, for every customer complaint or refund request received by defendant relating to any unapproved HIV test or other unapproved device, whether received directly or indirectly or through any third party, and to the extent that such information is available to defendant with reasonable inquiry: (1) the customer's name, address, telephone number and the dollar amount paid by the

customer; (2) the written complaint or refund request, if any, and the date of the complaint or refund request; (3) the basis of the complaint, including the name of any defendant or participating associate complained against, and the nature and result of any investigation conducted concerning any complaint; (4) each response and the date of the response; (5) any final resolution and the date of the resolution; and (6) in the event of a denial of a refund request, the reason for the denial; and

F. Copies of all advertisements, promotional materials, sales scripts, training materials, or other marketing materials utilized relating to any unapproved HIV test or other unapproved device.

IV. MONITORING

IT IS FURTHER STIPULATED AND ORDERED, in order to monitor compliance with this Order, that:

A. For a period of five (5) years from the date of entry of this Order, defendant shall deliver a copy of this Order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities involving the advertising, marketing, promotion, offering for sale, distribution or sale of any unapproved HIV test or other unapproved device, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. During this five (5) year period, defendant shall deliver this Order to such current personnel within ten (10) business days after the date of service of this Order, and to such future personnel within ten (10)

business days after the person assumes such position or responsibilities. Defendant shall maintain, and upon reasonable notice make available to representatives of the Commission, the original signed and dated acknowledgments of the receipt of the Order;

B. Sixty days (60) days after the date of entry of this Order, defendant shall provide a written report to the Commission, signed under penalty of perjury, detailing its past and present efforts to comply with this Order;

C. For a period of five (5) years from the date of entry of this Order, defendant shall notify the Commission of any proposed change in its structure, such as dissolution, assignment, sale, merger, creation or dissolution of subsidiaries, proposed filing of a bankruptcy petition, or change in the business or corporate name or address, or any other change that may affect compliance obligations arising out of this Order, thirty (30) days prior to the effective date of any proposed change; *provided, however,* that, with respect to any proposed change in Chembio 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 learning of such proposed change;

D. For a period of five (5) years from the date of entry of this Order, defendant shall notify the Commission, in writing, of any complaint or refund request defendant receives, whether received directly or indirectly or through any third party, related to the efficacy or accuracy of any unapproved HIV test advertised, marketed,

promoted, offered for sale, distributed or sold by defendant or its participating associates, directly or indirectly, or acting through any corporation, entity or person under its control. Such notification shall be made ***either*** by:

1. providing, in writing, to the Commission within five (5) business days of receipt by defendant and, shall include, but is not limited to, the following:
    a. a true and exact copy of the written complaint or refund request, including any documents accompanying the written complaint or refund request; if the complaint or refund request is made orally, such oral request shall be fully memorialized in writing by defendant and provided to the Commission;
    b. the name, address, telephone number, and e-mail address of the person or entity making the complaint or refund request received by defendant;
    c. the basis of the complaint or refund request, including the name of the defendant or participating associate complained against, the lot number of the unapproved HIV test complained against, and the nature and result of any investigation conducted concerning any complaint;
    d. any final resolution and the date of the resolution; ***and***
    e. in the event of a denial of a refund request, the reason for the denial;

provided that if defendant is unable, despite good faith efforts, to provide the Commission with any of the information enumerated in Section IV(D)(1)(a)-(e) within five (5) business days of receipt by defendant of any such complaint or refund request, defendant shall provide the Commission, in writing, with the reason(s) for its inability to provide the Commission with such information. Defendant shall provide the Commission with any supplemental materials within five (5) business days after receipt; ***or***

2. providing, in writing, to the Commission by the tenth day of each month ("reporting month") unredacted, true and correct copies of the following:

   a. the Monthly Complaint Log, currently known as Chembio's "Form FM101-2," in the form shown on Appendix A, for the month previous to the reporting month; ***and***

   b. the Complaint Record, currently known as Chembio's "Form FM101-1," in the form shown on Appendix B, for all complaints received for the month previous to the reporting month, including any documents or records produced in response to the received complaint; ***and***

   c. any Trend Analyses, reports or other documents produced in response to any complaint received by defendant or defendant's employees; ***and***

   d. any documents or records, not previously provided to the

Commission, that are prepared or produced in response to any complaint received in any month prior to the reporting month;

provided that should the tenth day of the month fall on a Saturday, Sunday, or federal holiday then all items enumerated in Section IV(D)(2)(a) - (d) shall be provided to the Commission in writing by the first business day after the tenth day of the month.

E. For a period of five years (5) from the date of entry of this Order, defendant shall permit representatives of the Commission, within three (3) business days of receipt of written notice from the Commission:

1. access during normal business hours to any office or facility storing any unapproved HIV test or other unapproved device advertised, marketed, promoted, offered for sale, distributed or sold by defendant or its participating associates, directly or indirectly, or acting through any corporation, entity or person under its control, to inspect and randomly select for testing by an expert designated by the Commission at least ten (10) unapproved HIV tests or other unapproved devices from each lot number then present at such office or facility;

2. access during normal business hours to any office, or facility storing documents, of any business owned by, or directly or indirectly under the control of, defendant, to inspect and copy all documents belonging to such business or defendant relating to the advertising, marketing, promotion,

offer for sale, distribution, or sale of any unapproved HIV test or other unapproved device; and shall permit Commission representatives to remove documents relating to the advertising, marketing, promotion, offer for sale, distribution, or sale of any unapproved HIV test or other unapproved device, for a period not to exceed five (5) business days so that the documents may be inspected, inventoried, and copied; *provided however* that nothing in this subsection shall constitute or require a waiver by defendant of any lawful privilege.

3. refrain from interfering with any duly authorized representatives of the Commission reasonably interviewing defendant's employers, employees (whether designated as employees, consultants, independent contractors or otherwise), or agents, about any matter relating to the advertising, marketing, promotion, offer for sale, distribution, or sale of any unapproved HIV test or other unapproved device; *provided however* that nothing in this subsection shall limit defendant, or defendant's employers, employees, or agents from having present, consulting with, and following the advice of legal counsel, or asserting any lawful privilege; and

4. upon reasonable written request by any duly authorized representative of the Commission, submit written reports (under oath, if requested), and produce documents, on five (5) business days notice, relating to the advertising, marketing, promotion, offer for sale, distribution, or sale of

any unapproved HIV test or other unapproved device; *provided however* that nothing in this subsection shall constitute or require a waiver by defendant of any lawful privilege.

F. The Commission is authorized to monitor the compliance of defendant with this Order by all lawful means, including but not limited to the following means:

1. The Commission is authorized, without further leave of court, to obtain discovery from any person in the manner provided by Chapter V of the Federal Rules of Civil Procedure, Fed. R. Civ. P. 26-37, including the use of compulsory process pursuant to Fed. R. Civ. P. 45, for the purpose of monitoring and investigating the compliance of defendant with this Order;

2. The Commission is authorized to use representatives posing as customers and suppliers to defendant, to defendant's employees, or to any other entity managed or controlled in whole or in part by defendant, without the necessity of identification or prior notice;

3. 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 investigate whether defendant has violated any provision of this Order or Sections 5 or 12 of the FTC Act, 15 U.S.C. §§45, 52;

G. Within five (5) business days of the entry of this Order, Haendler shall notify the Commission of (1) his residence address and mailing address; (2) his telephone

number(s); (3) the name, address and telephone number of his employers; (4) the full names of his employer's principals; (5) if applicable, the names of his supervisors; and (6) a description of his employer's activities, and his duties and responsibilities; and

H. For a period of five (5) years from the date of entry of this Order, Haendler shall notify the Commission within ten (10) business days of any changes in his residence or mailing addresses or employment status. Notice of changes in employment status shall include: (1) the new employer's name, address and telephone number; (2) the full names of the employer's principals; (3) if applicable, the names of his supervisor(s), and (4) a description of the employer's activities, and his duties and responsibilities;

V. COOPERATION WITH THE COMMISSION

IT IS FURTHER STIPULATED AND ORDERED that defendant shall, in connection with this action or any subsequent Commission investigations related to or associated with the transactions or the occurrences that are the subject of the Commission's complaint, cooperate in good faith with the Commission and appear at such places and times as the Commission shall reasonably request, after written notice to defendant or its counsel of record, for interviews, conferences, pretrial discovery, review of documents, and for such other matters as may be reasonably requested by the Commission. If requested in writing by the Commission, defendant shall appear and provide truthful testimony in any trial, deposition, or other proceeding related to or associated with the transactions or the occurrences that are the subject of the Complaint,

without the service of a subpoena; *provided however* that nothing in this subsection shall constitute or require a waiver by defendant of any lawful privilege.

VI. POTENTIAL ADDITIONAL OBLIGATIONS OF SPECIFIC INDIVIDUAL

IT IS FURTHER STIPULATED AND ORDERED that if Haendler ceases to be associated with defendant Chembio or any other business subject to this Order and is no longer a participating associate with regard to defendant Chembio or any other business subject to this Order, he will be bound, individually, by each and every provision of this Order if he engages, directly or indirectly, or through any corporation, entity, or person under his control, in the advertising, marketing, promotion, offering for sale, distribution or sale of any unapproved HIV test or other unapproved device. Nothing in this paragraph shall be construed to affect or limit any obligations Haendler may have under Federal Rule of Civil Procedure 65(d) or as a participating associate.

VII. ACKNOWLEDGMENT OF RECEIPT OF ORDER

IT IS FURTHER STIPULATED AND ORDERED that, within five (5) business days after receipt by defendant of this Order as entered by the Court, Haendler, individually and on behalf of defendant Chembio, shall execute and submit to the Commission a truthful sworn statement, in the form shown on Appendix C, that shall acknowledge receipt of this Order.

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VIII. RETENTION OF JURISDICTION

IT IS FURTHER STIPULATED AND ORDERED that this Court shall retain jurisdiction of this matter for purposes of construction, modification and enforcement of this Order. Defendant Chembio reserves the right to move for a modification of this Order in the future. The Commission reserves the right to oppose any such motion.

SO STIPULATED:

KAREN JAGIELSKI (KJ2103)
MAAME GYAMFI (MG2635)
Federal Trade Commission
600 Pennsylvania Ave., N.W.,
Room S-4002
Washington, D.C. 20580
(202) 326-2018, -2509 (voice)
(202) 326-3259 (facsimile)

CAROLE PAYNTER
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(212) 607-2813 (voice)
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Attorneys for Plaintiff
FEDERAL TRADE COMMISSION

TOMAS HAENDLER, President
Chembio Diagnostic Systems, Inc.

Individually, and on behalf of
CHEMBIO DIAGNOSTIC SYSTEMS, INC.

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(202) 637-5600 (voice)
(202) 637-5910 (facsimile)
Attorneys for Defendant

IT IS SO ORDERED this _____ day of _____, 2000.

UNITED STATES DISTRICT JUDGE

APPENDIX A

See Attached Blank Monthly Complaint Log

APPENDIX B

See Attached Blank Monthly Complaint Record

APPENDIX C

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, Plaintiff, v. CHEMBIO DIAGNOSTIC SYSTEMS, INC., Defendant.	Case No. **AFFIDAVIT OF TOMAS HAENDLER**

Tomas Haendler being duly sworn, hereby states and affirms as follows:

1.My name is Tomas Haendler. I am a citizen of the United States and am over the age of eighteen. I have personal knowledge of the facts set forth in this Affidavit, and if called as a witness, I could and would competently testify as to the matter stated herein.

2.My current business address is _____. My current business telephone number is _____. My current residential address is _____. My current residential telephone number is _____.

3.I am the President of defendant Chembio Diagnostic Systems, Inc. If I cease to be associated with defendant Chembio or any other business subject to this Order and am no longer a participating associate with respect to Chembio or any other business subject to this order, I will continue to be bound, individually, by each and every provision of this Order if I engage, directly or indirectly, or through any corporation, entity, or person under my control, in the advertising,

marketing, promotion, offering for sale, distribution or sale of any unapproved HIV test or other unapproved device.

4.On [date], I received, individually, and on behalf of Chembio Diagnostic Systems, Inc., a copy of the Stipulated Final Order for Permanent Injunction and Other Equitable Relief, which was signed by the Honorable [name of Judge] and entered by the Court on [date of entry of Order]. A true and correct copy of the Order that I received is appended to this Affidavit.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed on [date], at [city and state].

_____

Tomas Haendler

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

SUBSCRIBED AND SWORN to before me this _____ day of _____, 2000, by Tomas Haendler. He is personally known to me or has presented (state identification) _____ _____ as identification.

_____

PRINT NAME

NOTARY PUBLIC,Commission Number

STATE OF _____My Commission Expires: _____

Affix Seal