UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, Plaintiff, v. MAIN STREET FAMILY PHARMACY, LLC, a corporation, and DAVID A. NEWBAKER and CHRISTY R. NEWBAKER, individuals, Defendants.	)	No. CONSENT DECREE OF PERMANENT INJUNCTION

The United States of America, plaintiff, by its undersigned attorneys, having filed its complaint for injunctive relief against Defendants, Main Street Family Pharmacy, LLC, ("Main Street"), a limited liability corporation, and David A. and Christy R. Newbaker, individuals (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree"), without contest, without admitting or denying the allegations in the Complaint, and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331 and 1345 and 21 U.S.C. § 332 and its inherent equitable authority.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399f (the "Act").

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(d), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval.

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(1), in that they consist in whole or in part of a filthy, putrid, or decomposed substance.

5. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug, that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that the drugs have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health.

6. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of drugs do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that they meet the requirements of the Act as to their safety and that they have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

7. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(b), in that they purport to be or are represented as drugs the names of which are recognized in an official compendium and their quality and/or purity fall below the standards set forth in such compendium.

8. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(a), in that their labeling is false or misleading.

9. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that their labeling does not bear adequate directions for use.

10. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are misbranded within the meaning of 21 U.S.C. §352(j), in that they are dangerous to health when used in a dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; and

11. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A), 351(a)(2)(B) and/or 21 U.S.C. § 351(b), and to

become misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(j) and 352(f)(1), while the drugs are held for sale after shipment of one or more of their components in interstate commerce.

12. For purposes of this Decree, the following definitions shall apply:

A. "CGMP" shall refer to the current good manufacturing practice requirements for drugs set forth in 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211. If Defendants elect to register Defendants' facility as an outsourcing facility under 21 U.S.C. § 353b as provided in paragraph 16, then in determining whether Defendants are compounding drugs at an outsourcing facility in compliance with CGMP, Defendants, their expert consultants, and FDA may consider any regulations and/or guidance that FDA has issued with respect to CGMP for outsourcing facilities;

B. "Compound" and "compounding" shall include the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug;

C. "Days" shall refer to calendar days unless otherwise stated;

D. "Defendants' facility" shall refer to the facility located at 126 East Main Street, Newbern, TN 38059, and any other location(s) at which Defendants manufacture, hold and/or distribute articles of drug on their own behalf or on the behalf of any business association(s) in which they have a legal interest and/or have any supervisory or management responsibilities;

E. "Drug" shall have the meaning given the term in 21 U.S.C. § 321(g)(1);

F. "Drug product" shall mean a finished dosage form (for example, tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients;

G. "FDA" shall mean the United States Food and Drug Administration;

H. The terms "manufacture," "manufactured," and "manufacturing" shall include manufacturing, compounding, processing, packing, repacking, and labeling drugs;

I. "New drug" shall have the meaning given the term in 21 U.S.C. § 321(p); and

J. "Sterile drug" shall have the meaning given the term in 21 U.S.C. § 353b(d)(5).

13. Defendants represent that they are discontinuing all operations related to the manufacture, holding or distribution of drugs at Defendants' facility. Defendants further represent that, if they later elect to resume operations at Defendants' facility, they intend to only manufacture drugs that are compounded in compliance with 21 U.S.C. § 353a in order to attempt to qualify for the exemptions from 21 U.S.C. §§ 351(a)(2)(B), 352(f)(1), and 355 and will do so only after completing all the requirements set forth in paragraph 14 and after receiving written notification from FDA under paragraph 14.I.

14. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly manufacturing, and/or holding or distributing any drugs manufactured at the Defendants' facility, unless and until:

A. Defendants' facilities, methods, and controls used to manufacture, hold, and/or distribute drugs are established, operated, and administered in conformity with the Act, and

its implementing regulations, and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A), and/or 351(b), or misbranded within the meaning of 21 U.S.C. § 352(a) and/or 352(j);

B. Defendants retain, at Defendants' expense, an independent person or persons (the "Drug Compliance Expert"), who: (i) is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this provision, or retention agreements entered into prior to the entry of this Decree) to Defendants or their families; and (ii) by reason of background, training, education, or experience, is qualified to inspect the Defendants' facilities to determine whether Defendants' facilities, equipment, processes, and procedures are adequate to prevent Defendants from manufacturing, holding, and/or distributing drug products that are adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A), and/or 351(b), and/or misbranded within the meaning of 21 U.S.C. §§ 352(a) and/or 352(j). Defendants shall notify FDA in writing of the identity and qualifications of the Drug Compliance Expert within ten (10) days of retaining any such Drug Compliance Expert;

C. The Drug Compliance Expert performs a comprehensive inspection of the Defendants' facilities and the equipment, processes and procedures used to manufacture, hold, and/or distribute drugs to determine whether such facilities, equipment, processes, and procedures are adequate to prevent Defendants' drug products from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A) and/or 351(b), and/or misbranded within the meaning of 21 U.S.C. §§ 352(a) and/or 351(j), including, but not limited to, whether:

i. Defendants' facility is adequately designed for the manufacture of aseptically processed drugs with adequate separation, defined functional areas, and/or other such control systems necessary to prevent contamination or mix-ups;

ii. Defendants have thoroughly and adequately cleaned and sanitized (and sterilized, as appropriate) the manufacturing areas of Defendants' facility, including, but not limited to, equipment and utensils used in the manufacture and/or holding of Defendants' drugs;

iii. Defendants have excluded pests—including, but not limited to, vermin—from aseptic processing areas and areas adjacent to aseptic processing areas;

iv. Defendants ensure that Defendants' facility is suitably designed, with respect to the flow of personnel, in-process materials, and finished drugs; the need for room segregation and process separation; and the impact from heating ventilation and air conditioning (HVAC), air pressurization, and unidirectional airflow, to prevent contamination and other hazards to sterile drugs;

v. Defendants have ensured that the equipment used in the manufacture and/or holding of Defendants' drugs is designed to facilitate appropriate operations, cleaning, and maintenance;

vi. Defendants have established and follow adequate written standard operating procedures (SOPs) to ensure proper maintenance of aseptic processing areas and equipment used therein;

vii. Defendants' cleaning and disinfection solutions and procedures are validated and shown to be effective for their intended purposes;

viii. Defendants have established and implemented adequate procedures designed to prevent microbiological contamination of drugs purporting to be sterile, including, but not limited to, operational procedures, procedures for dynamic smoke studies, sterilization processes, and procedures for conducting appropriate media fill simulations;

ix. Defendants have established and implemented an adequate environmental monitoring program to (a) ensure that all aseptic operations in the Defendants' facility are properly monitored (including personnel, particles , surfaces, and air quality), and (b) identify and address any results beyond scientifically sound and appropriate pre-established limits and adverse trends; and

x. Defendants have established, and Defendants' manufacturing personnel follow, SOPs for manufacturing personnel practices adequate to protect drug products from contamination, including, but not limited to, ensuring appropriate use of sterile gowning components.

D. The Drug Compliance Expert certifies in writing to FDA and the Defendants that: (1) he/she has inspected Defendants' facilities, equipment, processes, and procedures; and (2) Defendants have undertaken corrective actions to ensure that their facilities, equipment, processes, and procedures are adequate to prevent their drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(1) , 351(a)(2)(A), and/or 351(b), and/or misbranded within the meaning of 21 U.S.C. §§ 352(a) and/or 352(j). As part of this certification, the Drug Compliance Expert shall include a detailed and complete report of the results of the inspections conducted under paragraph 14.C of this Decree;

E. Defendants establish and maintain a system to report to FDA through the MedWatch reporting system all adverse drug experiences (in the manner described in 21 C.F.R. § 310.305 and/or in 21 C.F.R. § 314.80) associated or potentially associated with any and all of Defendants' drugs as soon as possible, but no later than fifteen (15) days after initial receipt of the information;

F. Defendants establish and maintain a system to submit to FDA, at the address specified in paragraph 32, Field Alert Reports (in the manner and as described in 21 C.F.R. § 314.81(b)(1)) for all of Defendants' distributed drug products within three (3) working days from initial receipt of the information triggering the Field Alert Report;

G. Defendants report to FDA in writing the actions they have taken to:

i. Correct all of the deviations brought to Defendants' attention by FDA, the Drug Compliance Expert, or any other source; and

ii. Ensure that Defendants' facility, equipment, processes, and procedures the methods used to manufacture, hold, and/or distribute drugs will be continuously administered and operated in conformity with this Decree, the Act, and its implementing regulations, and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(1), 351(a)(2)(A) and/or 351(b), and/or or misbranded within the meaning of 21 U.S.C. §§ 352(a) and/or 352(j);

H. FDA representatives, without prior notice and as and when FDA deems necessary, inspect the Defendants' facility to determine whether Defendants are in compliance with the requirements of the Act, its implementing regulations, and this Decree, including but not limited to whether Defendants' facility, equipment, processes, and procedures are adequate to prevent their drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A) and/or 351(b), or misbranded within the meaning of 21 U.S.C. §§ 352(a) and/or 352(j);

I. Following inspection(s) by FDA, FDA notifies Defendants in writing that Defendants appear to be in compliance with all of the requirements set forth in paragraphs 14.A –

14.G of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

15. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under 21 U.S.C. § 332(a), from directly or indirectly manufacturing any drug at Defendants' facility unless such drug is compounded in compliance with 21 U.S.C. § 353a, including, but not limited to, the following:

A. The drug product shall:

i. Be compounded for an identified individual patient either: (a) based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient; or (b) before the receipt of a valid prescription order for an individual patient, provided that the compounding is performed only in limited quantities and based on a history of receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between Defendants and either (i) the individual patient for whom the prescription order will be provided, or (ii) the physician or other licensed practitioner who will write such prescription order; and

ii. Not be distributed by Defendants prior to receipt of a valid prescription order for the identified patient;

B. Defendants shall compound the drug product using only approved drug products or bulk drug substances that meet the conditions in 21 U.S.C. § 353a(b)(1)(A)(i), (ii), & (iii), and/or other ingredients that meet the conditions in 21 U.S.C. § 353a(b)(1)(B);

C. Defendants shall not compound regularly or in inordinate amounts any drug product that is essentially a copy of a commercially available drug product, as defined in 21 U.S.C. § 353a(b)(2);

D. Defendants shall not compound a drug product that appears on any existing or future list published by FDA in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

E. Defendants shall not compound any drug product that is identified by FDA by existing or future regulation as a drug product that presents demonstrable difficulties for compounding;

F. Defendants shall compound drug products in conformance with 21 U.S.C. § 353a(b)(3)(B), after FDA finalizes a memorandum of understanding and makes it available to the States for their consideration and signature and after the time period FDA allows for states to consider whether to sign the memorandum of understanding; and

G. Defendants shall compound the drug product in compliance with the United States Pharmacopoeia (USP) chapters on pharmacy compounding, including but not limited to USP <797>, USP <795>, and any other current or future chapters of the USP that are applicable to compounding drugs.

16. Notwithstanding paragraph 15, at any time following receipt of the notification pursuant to paragraph 14.I, Defendants may elect to register Defendants' facility as an

outsourcing facility under 21 U.S.C. § 353b and manufacture drugs that are compounded in compliance with all of the requirements in 21 U.S.C. § 353b. Prior to compounding as an outsourcing facility any drug for human use, Defendants shall:

A. Notify FDA in writing of their intent to register and operate as an outsourcing facility;

B. Ensure that each and every drug that Defendants intend to compound, hold, and/or distribute at or from Defendants' facility satisfies all of the conditions set forth in 21 U.S.C. § 353b, including but not limited to the requirements regarding:

i. Drug labeling at 21 U.S.C. § 353b(a)(10);

ii. Facility registration at 21 U.S.C. § 353b(b)(1);

iii. Use of bulk drug substances at 21 U.S.C. § 353b(a)(2);

iv. Drug reporting at 21 U.S.C. § 353b(b)(2); and

v. Adverse event reporting at 21 U.S.C. § 353b(b)(5);

C. Ensure that the facilities, methods, and controls used to compound, hold, and/or distribute Defendants' drugs are established, operated, and administered in conformity with CGMP;

D. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP Expert"), who: (1) is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this provision, or retention agreements entered into prior to the entry of this Decree) to Defendants or their families; and (2) by reason of background, training, education, or experience, is qualified to conduct inspections to determine whether Defendants' facility, methods, and controls are established, operated, and administered in conformity with CGMP, and to recommend corrective actions. Defendants

shall notify FDA in writing of the identity and qualifications of the CGMP Expert within ten (10) days after retaining any such CGMP Expert;

E. Defendants submit a protocol that identifies the work plan for the CGMP Expert and the methodology that shall be used by the CGMP Expert (the "Work Plan") to: (1) conduct inspection(s) of Defendants' facility as described in paragraph 16.D; (2) ensure that Defendants implement all recommended corrective actions; and (3) ensure that Defendants' manufacture, holding, and distribution of drugs will be continuously administered in conformity with CGMP. Defendants shall not implement the work plan prior to receiving FDA's written approval of such work plan;

F. The CGMP Expert reviews all observations listed on the Form FDA-483 issued to Defendants on June 11, 2013, and performs a comprehensive inspection(s) of Defendants' facility and the methods and controls used to manufacture, hold, and/or distribute drugs to determine whether such facilities, methods, and controls are, at a minimum, in conformity with CGMP. The CGMP Expert shall, at a minimum, evaluate whether:

i. Defendants have cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized equipment and utensils at appropriate intervals to prevent malfunctions or contamination;

ii. Defendants have established an adequate system for monitoring environmental conditions;

iii. Defendants have established and implemented appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, including the validation of all aseptic and sterilization processes;

iv. Defendants ensure that personnel engaged in the manufacture, processing, packing, or holding of drug products wear clean clothing appropriate for the duties they perform, and that protective apparel, such as head, face, hand, and arm coverings, are worn as necessary to protect drug products from contamination;

v. Defendants have established and implemented an adequate written testing program designed to assess the stability characteristics of their drug products;

vi. Defendants have, for each batch of drug product purporting to be sterile and/or pyrogen-free, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product;

vii. Defendants thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed;

viii. Defendants obtain and retain, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient prior to release; and

ix. Defendants conform to written procedures for production and process control designed to assure that the drug products manufactured have the identity, strength, quality, and purity they purport or are represented to possess;

G. The CGMP Expert certifies in writing to FDA and Defendants that:

i. The CGMP Expert has inspected Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute drugs;

ii. All deviations from CGMP brought to Defendants' attention by FDA, the CGMP Expert, or any other source have been corrected; and

iii. Defendants' facility, methods, and controls comply with CGMP.

As part of this certification, the CGMP Expert shall include a detailed and complete report of the results of the CGMP Expert's inspection(s) conducted under this paragraph;

H. Defendants report to FDA in writing the actions they have taken to:

i. Correct all deviations from CGMP brought to Defendants' attention by FDA, the CGMP Expert, or any other source; and

ii. Ensure that Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute drugs are established, operated, and administered in conformity with CGMP;

I. Defendants establish and maintain a system to report to FDA through the MedWatch reporting system all adverse drug experiences (in the manner described in 21 C.F.R. § 310.305 and/or 21 C.F.R. § 314.80) associated or potentially associated with any and all of Defendants' drugs as soon as possible, but no later than fifteen (15) days after initial receipt of the information;

J. Defendants establish and maintain a system to submit to FDA, at the address specified in paragraph 32, Field Alert Reports (in the manner and as described in 21 C.F.R. § 314.81(b)(1)) for all of Defendants' distributed drugs within three (3) working days after initial receipt of the information triggering the Field Alert Report;

K. FDA representatives, without prior notice and when FDA deems necessary, inspect Defendants' facility to determine whether Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute drugs are established, operated, and administered in conformity with CGMP; and

L. Following inspection(s) by FDA, Defendants receive written notice from FDA that Defendants appear to be in compliance with all of the requirements set forth in paragraphs 16.A-16.J. In no circumstance shall FDA's silence be construed as a substitute for written notification.

17. Paragraphs 15 and 16 do not prohibit Defendants from manufacturing any drug for which they are the sponsor of an application approved pursuant to 21 U.S.C. § 355, provided that Defendants have received the notification pursuant to paragraph 14.I, and comply with all statutory and regulatory requirements applicable to manufacturing such drugs, including but not limited to CGMP.

18. After Defendants have complied with paragraph 14 and have received written notification from FDA under paragraph 14.I, Defendants shall retain an independent person who meets the criteria described in paragraph 14.B and is qualified to assess Defendants' compliance with paragraph 15 (the "Auditor") to conduct audit inspections of Defendants' facility. If Defendants elect to operate Defendants' facility as an outsourcing facility under 21 U.S.C. § 353b, for all audit inspections conducted after such election, Defendants shall retain as the Auditor an independent person who meets the criteria described in paragraph 16.D and who is qualified to assess Defendants' compliance with paragraph 16. Defendants shall notify FDA in writing as to the identity and qualifications of the Auditor as soon as they retain such Auditor. After Defendants receive written notification from FDA under paragraph 14.I, audit inspections under this paragraph shall commence no less frequently than once every four (4) months for a period of one (1) year, and once every six (6) months thereafter for an additional four (4) year period:

A. At the conclusion of each audit inspection described in this paragraph, the Auditor shall prepare a written audit report ("Audit Report") analyzing whether Defendants comply with the requirements of this Decree, the Act, and its implementing regulations. The Audit Report(s) shall identify all deviations from this Decree, the Act, and its implementing regulations ("audit report observations"). Beginning with the second Audit Report, the Auditor shall also assess the adequacy of any corrective actions taken by Defendants to correct all previous audit report observations, and include this information in the Audit Report(s). The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service no later than fifteen (15) days after the date each audit inspection is completed. In addition, Defendants shall maintain the Audit Reports in a separate file at Defendants' facility to which the report pertains and shall promptly make the Audit Reports available to FDA upon request; and

B. If an Audit Report contains any audit report observations, Defendants shall, within thirty (30) days after receipt of the Audit Report, correct those deviations, unless FDA notifies Defendants in writing that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations will take longer than thirty (30) days, Defendants shall, within ten (10) business days after receipt of the audit report, propose a schedule for completing corrections. FDA shall, as it deems appropriate, review and approve the proposed schedule in writing prior to implementation. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) days after Defendants' receipt of an Audit Report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the

Auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the audit report observations has been fully corrected and, if not, which audit report observations remain uncorrected.

19. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(d) by introducing and/or causing the introduction into interstate commerce, and/or delivering and/or causing the delivery for introduction into interstate commerce, any new drug that is neither approved under 21 U.S.C. § 355(a), nor exempt from approval;

B. Violates 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A), 351(b), and/or 351(a)(2)(B), and/or misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(j), and/or 352(f)(1);

C. Violates 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A), 351(b), and/or 351(a)(2)(B), or misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(j), and/or 352(f)(1) while such drug is held for sale after shipment of one or more of its components in interstate commerce; and/or

D. Any act that results in the failure to implement and continuously maintain the requirements of this Decree.

20. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analyses of samples, a report or data prepared or submitted by Defendants, the Drug Compliance Expert, the CGMP expert, or the Auditor, or any other information, that Defendants have failed to comply with the provisions of this Decree, violated the Act and/or its implementing regulations, and/or or that additional corrective actions are necessary to achieve compliance with this Decree, the Act and/or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease all manufacturing, holding, and/or distributing of any and all drug(s);

B. Recall specified drugs manufactured, held, and/or distributed by Defendants. The recall(s) shall be initiated within twenty-four (24) hours after receiving notice from FDA that a recall is necessary. Defendants shall, under FDA supervision, destroy all finished and/or in-process drugs and components that are in Defendants' possession, custody, or control, for which a recall was initiated. Defendants shall bear the costs of such recall(s), including the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 23. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state law;

C. Submit additional reports or information to FDA;

D. Repeat, revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

E. Issue a safety alert with respect to a drug manufactured, held, or distributed by Defendants;

F. Pay liquidated damages as provided in paragraph 29; and/or

G. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree or the Act.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

21. Any cessation of operations or other action described in paragraph 20 shall be implemented immediately and continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Decree, and that Defendants may resume operations. Upon Defendants' written request to resume operations, FDA will determine whether Defendants appear to be in such compliance and, if so, issue to Defendants a written notification permitting, as appropriate, resumption of operations. In no circumstance shall FDA's silence be construed as a substitute for written notification. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraph 20 shall be borne by Defendants at the rates specified in paragraph 23. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

22. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Defendants' facilities, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to the Defendants' facilities including, but not limited to, all buildings, equipment, in-process or unfinished and finished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples – without charge to FDA – of Defendants' finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material; and to examine and copy all records relating to the receipt, manufacturing, holding, and distribution of any and all drugs and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

23. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $88.45 per hour and fraction thereof per representative for inspection work; $106.03 per hour or fraction thereof per representative for analytical or review work; $0.56 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the

standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

24. Within three (3) days after becoming aware of any of the following information about any drugs manufactured, held and/or distributed at Defendants' facility , Defendants shall submit to FDA, at the address specified in paragraph 32, a product quality report describing all information pertaining to any:

A. Product and/or manufacturing defects that could result in serious adverse drug experiences;

B. Incident(s) that causes any drug or its labeling to be mistaken for, or applied to, another article; and/or

C. Contamination, including any bacteriological or fungal contamination, or any significant chemical, physical, or other change or deterioration in any drug.

25. Within seven (7) days after entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in the employee common areas at Defendants' facility. Defendants shall ensure that the Decree remains posted at Defendants' facility for as long as the Decree remains in effect.

26. Within seven (7) days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or registered mail, to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (collectively referred to as "Associated Persons"). Within thirty (30) days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating

the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

27. In the event that any of the Defendants become associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within thirty (30) days of each time any of the Defendants becomes associated with any such additional Associated Person(s), Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within seven (7) days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

28. Defendants shall notify FDA at least fifteen (15) days before any change in ownership, character, or name of their businesses, including incorporation, reorganization, bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure or identity of Main Street, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any potential successor or assign at least fifteen (15) days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) days prior to such assignment or change in ownership.

29. If Defendants fail to comply with any of the provisions of this Decree with respect to Defendants' facility or any drug products manufactured, held, or distributed at Defendants' facility, including any time frame imposed by this Decree, then, upon receipt of an order issued under paragraph 20, Defendants shall pay to the United States of America: fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues; an additional sum of fifteen thousand dollars ($15,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree; and further additional sum equal to the retail value of drug products that have been distributed in violation of this Decree. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

30. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

31. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall pay all attorneys' fees and costs, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, and court costs incurred by Plaintiff in bringing such an action.

32. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be marked "Consent Decree

Correspondence" and shall be addressed to the Director, FDA New Orleans District Office, 404 BNA Drive, Building 200, Suite 500, Nashville, Tennessee 37217.

33. If any deadline in this Decree falls on a weekend or holiday, the deadline is continued to the next business day.

34. This Decree resolves only those claims set forth in the Complaint in this action, and does not affect any other civil, criminal, or administrative claims that the government may have or bring in the future against the Defendant herein.

35. This Court retains jurisdiction of this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this _____ day of _____, 2014.

_____

UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

FOR DEFENDANTS

DAVID A. NEWBAKER
Individually and on behalf of
MAIN STREET FAMILY PHARMACY,
LLC

CHRISTY R. NEWBAKER
Individually and on behalf of
MAIN STREET FAMILY PHARMACY,
LLC

ALEX LITTLE
Bone McAllester Norton PLLC
511 Union Street, Suite 1600
Nashville, TN 37219
Tel: (615) 238-6395
Attorney for Defendants

FOR PLAINTIFF

EDWARD L. STANTON III
United States Attorney

STUART CANALE
Assistant United States Attorney
167 North Main Street, Suite 800
Memphis, TN, 38103
Tel: (901) 544-4231

JOYCE R. BRANDA
Acting Assistant Attorney General

JONATHAN F. OLIN
Deputy Assistant Attorney General

MICHAEL S. BLUME
Director

DAVID SULLIVAN
Trial Attorney
Consumer Protection Branch
Department of Justice
P.O. Box 386
Washington, D.C. 20044

Of Counsel:
WILLIAM B. SCHULTZ
General Counsel

ELIZABETH DICKINSON
Chief Counsel, Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

SONIA W. NATH
Associate Chief Counsel
U. S. Department of Health and Human Services
Office of the General Counsel
Food and Drug Administration
Building 31, Room 4568
10903 New Hampshire Avenue
Silver Spring, MD 20993
(301) 796-8708