UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA

Plaintiff,

v.

No. 09-12498

All articles of drug, including active and inactive pharmaceutical components and in-process materials and components, in any size and type of container, labeled or unlabeled (excluding sealed containers of active and inactive pharmaceutical components; any finished drug product manufactured by Sun Pharmaceutical Industries, Ltd., which may be distinguished by lot numbers containing JK or GK in the initial digits; and the following finished drug products that are manufactured by Sun Pharmaceuticals, Inc., Pharmaceutics International, Inc., or Mikart, Inc.:
Benzonatate Caps 100mg, 100ct;
Benzonatate Caps 200mg, 100ct;
Bethanechol Tabs 5mg, 100ct;
Bethanechol Tabs 10mg, 100ct;
Bethanechol Tabs 25mg, 100ct
Bethanechol Tabs 50mg, 100ct;
Gemfibrozil Tabs 600mg, 60ct;
Gemfibrozil Tabs 600mg, 500ct;
Hydrocodone w/APAP C-III Tabs 5 mg/325mg, 100ct;
Hydrocodone w/APAP C-III Tabs 5mg/325mg, 500 ct;
Hydrocodone w/APAP C-III Tabs 7.5mg/325mg, 100ct;
Hydrocodone w/APAP C-III Tabs 7.5mg/325mg,

500 ct;
Hydrocodone w/APAP C-III Tabs 10mg/325mg,
100 ct;
Hydrocodone w/APAP C-III Tabs 10mg/325mg,
500ct;
Nimodipine Caps 30mg, 30UD;
Nimodipine Caps 30mg, 100UD;
Oxycodone HCl C-II Tabs 5mg, 100ct;
Oxycodone HCl C-II Tabs 15mg, 100ct;
Oxycodone HCl C-II Tabs 30mg, 100ct;
Promethazine HCl Oral Solution (Syrup)
6.25mg/5mL, 4oz;
Promethazine HCl Oral Solution (Syrup)
6.25mg/5mL, 16 oz;
Promethazine HCl Tabs 12.5mg, 100ct;
Promethazine HCl Tabs 25mg, 100ct;
Promethazine HCl Tabs 50mg, 100ct;
Synalgos DC Caps 16mg/356.4mg/30mg, 100ct;
Hydrocodone/APAP 100ct; and
Hydrocodone/APAP 500ct), which are located anywhere
on the premises of
Caraco Pharmaceutical Laboratories, Ltd.,
1150 Elijah McCoy Drive, Detroit, Michigan,
24700 Crestview Court, Farmington Hills, Michigan,
and 31060 Oak Creek Drive, Wixom, Michigan,
to which may be affixed labels bearing,
among other things, the name and address
of the manufacturer, packer, or distributor
located outside the State of Michigan, or
which are otherwise determined to consist
of whole or in part of components that have
originated outside the State of Michigan,

Defendants.

_____/

CONSENT DECREE OF CONDEMNATION, FORFEITURE, AND PERMANENT INJUNCTION

On June 24, 2009, the United States of America, plaintiff, filed a Verified Complaint for Forfeiture against the articles described in the above caption.

On June 25, 2009, this Court issued a Warrant for Arrest in rem directing the United States Marshal for this district to seize the articles. The U.S. Marshal executed the seizure on June 25, 2009. Thereafter, the United States caused notice of the complaint and seizure to be published in accordance with the applicable rules of this Court.

On July 13, 2009, the United States amended its Complaint to exclude from the seizure certain products that were manufactured by third parties and only distributed by Caraco.

The articles proceeded against are articles of drug within the meaning of the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 321(g)(1). The amended complaint alleges that the seized articles are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with current good manufacturing practice ("CGMP") requirements for drugs. See 21 C.F.R. Parts 210 and 211.

On July 15, 2009, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco" or "Claimant") intervened and filed a claim to all of the seized articles. No other party filed a claim to the seized articles within the time allowed pursuant to Rule G of the Supplemental Rules for Admiralty or Maritime Claims and Asset Forfeiture Actions.

Claimant, having appeared and voluntarily consented to the entry of this Decree without contest, solely for the purposes of settling this case, without admitting any of the allegations of the Complaint, and before any testimony has been taken, and waiving the filing and service of

an amended complaint seeking injunctive relief, and the United States having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. §§ 332 and 334, and personal jurisdiction over all parties to this action.

2. Claimant affirms that it is the sole owner of the seized articles, and it shall hold the United States harmless should any party or parties hereafter file or seek to file a claim or to intervene in this action and obtain any part of the seized articles.

3. The complaint alleges that the seized articles are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with current good manufacturing practice (CGMP) requirements for drugs, 21 C.F.R. Part 211.

4. The seized articles are therefore condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

5. Pursuant to 21 U.S.C. § 334(d), Claimant shall pay to the United States all court costs and fees, storage, and other proper expenses to date, and such additional expenses as may hereinafter be incurred and taxed. Claimant shall pay these costs in full within thirty (30) calendar days of receiving written notice from the Food and Drug Administration ("FDA") of such costs.

6. Nothing in this Decree shall prohibit Claimant from distributing any FDA-approved drug products that are manufactured or processed, held, or distributed at or by a third party or parties, so long as Caraco did not perform any manufacturing or processing functions with respect to such drugs, and Claimant's responsibility is that of a distributor, including hydrocodone/APAP 10 mg/660 mg. (100 ct) and 10 mg./660 mg. (500 count), manufactured by Sun Pharmaceuticals Industries, Inc.; nor shall this Decree prevent Claimant from distributing, promethazine with codeine, manufactured by Sun Pharmaceuticals Industries Inc., once the product receives ANDA approval.

7. Upon notification from the United States Attorney, the United States Marshal for this District shall release the appropriate Lot of Articles (as described in subparagraphs A-C of this paragraph) from his custody to the custody of the Claimant for the sole purpose of attempting to bring the Articles into compliance with the Act, if Claimant, within twenty (20) calendar days from the date of this Decree, (a) pays in full the court costs, fees, and storage and other proper expenses of this proceeding to date as described in paragraph 5 of this Decree; and (b) executes and files with the Clerk of this Court a good and sufficient penal bond in the form of a bond or an irrevocable standby letter of credit in the amount of fifteen million dollars ($15,000,000) to be applied to Lot 1 (as described in Subpart A of this paragraph) and held for application to succeeding Lots 2-3 (as described in subparagraphs B-C of this paragraph), payable to the United States of America, and conditioned on the Claimant's abiding by and performing all of the terms and conditions of this Decree and such further orders and decrees as may be entered in this proceeding. Said irrevocable standby letter of credit shall be obtained from a trust company or a commercial bank in good standing, shall be valid for at least ninety (90) calendar days from the date this Decree is entered, shall be approved by this Court, and may

be drawn upon by the presentation of a sight draft. The schedule for release of the Articles is as follows:

A. The Articles in Lot 1, consisting of raw materials that have been opened by Claimant for the limited purpose of quality control sampling, which represent approximately one-third of the articles (by value), to be further designated by the FDA representative, shall be released to Claimant for the purpose of attempting to bring Lot 1 into compliance with the law, following payment of the costs described in Paragraph 5 and the filing of the bond or irrevocable standby letter of credit.

B. If and only if Claimant complies with all of the terms of this Decree with respect to Lot 1, and Lot 1 has been released in writing by FDA, the Articles in Lot 2, consisting of approximately a second one-third of the seized articles (by value), to be further designated by the FDA representative, shall be released to Claimant for the purpose of attempting to bring Lot 2 into compliance with the law.

C. If and only if Claimant complies with all of the terms of this Decree with respect to Lot 2, and Lot 2 has been released in writing by FDA, the Articles in Lot 3, consisting of the remaining seized Articles, shall be released to Claimant for the purpose of attempting to bring Lot 3 into compliance with the law.

D. If Claimant will not be able to complete the process of attempting to bring the Articles into compliance with the law prior to the expiration of the original bond or irrevocable standby letter of credit, or any subsequent bond or irrevocable standby letter of credit, it shall be the responsibility of Claimant to file with the Clerk of this Court a new bond or irrevocable standby letter of credit in the amount of fifteen million dollars ($15,000,000), valid for at least an additional ninety (90) calendar days, no later than five (5) calendar days before the

expiration of the previous bond or irrevocable standby letter of credit, and to provide written notice of the posting of such new bond or letter of credit to both FDA and the United States Attorney. If, five (5) calendar days before the expiration of the original bond or irrevocable standby letter of credit, or any subsequent bond or irrevocable standby letter of credit, Claimant has not completed the process of bringing the Articles into compliance with the law and Claimant has not filed a new bond or irrevocable standby letter of credit with the Clerk of this Court, the existing bond or irrevocable standby letter of credit shall be forfeited and immediately payable to the United States of America prior to expiration of such irrevocable standby letter of credit.

8. Claimant shall at all times, until the Articles have been released by an FDA representative, retain intact each Lot of articles seized for examination or inspection by the FDA representative, and shall maintain the records or other proof necessary to establish the identity of the Articles comprising each Lot to the satisfaction of the FDA representative.

9. After paying the costs pursuant to paragraph 5 above and filing the bond with the clerk of this court pursuant to paragraph 7 above, Claimant shall give written notice to FDA that Claimant, at its own expense, is prepared to attempt to bring the condemned articles into compliance with the law under the supervision of a duly authorized FDA representative.

10. Claimant shall not commence, permit any other person to commence, or cause any other person to commence attempting to bring the condemned articles into compliance with the law unless and until Claimant (a) submits a written statement to FDA detailing Claimant's proposed plan to bring the condemned articles into compliance with the law (the "Proposal"); (b) receives written approval of the Proposal from FDA with authorization from FDA to commence attempting to bring the condemned articles into compliance with the law. The FDA shall respond

in writing to Claimant's Proposal, approving or disapproving the Proposal, within twenty (20) calendar days of receipt.

For purposes of the articles in Lot 1 only, Claimant may submit a certification from its CGMP expert that the articles in Lot 1 are in compliance with the law, in lieu of a Proposal in paragraph 10(a). Such certification shall include the bases for the certification. FDA shall approve or disapprove of such certification within fifteen (15) calendar days of receipt. If FDA approves such certification for any articles in Lot 1, FDA shall release such articles. If FDA does not approve the certification for any of the articles in Lot 1, such articles shall be subject to paragraph 10(a) and (b).

11. Within five (5) calendar days of the FDA's written approval and authorization identified in paragraph 10, the United States Attorney shall notify the United States Marshal for this District that FDA has authorized the Claimant to commence reconditioning. The Marshal shall release the condemned articles from his custody to the custody of Claimant for the sole purpose of attempting to bring such articles into compliance with the law pursuant to the Proposal described in paragraph 10.

12. Claimant shall at all times, until the condemned articles have been released in writing by an FDA representative, retain the condemned articles intact for examination or inspection by the FDA representative in a place made known to and approved by FDA, and shall maintain the records or other proof necessary to establish the identity of the articles to the satisfaction of the FDA representative.

13. Within sixty (60) calendar days of receiving written authorization to commence attempting to bring the condemned articles into compliance with the law, Claimant shall complete its attempt to bring the condemned articles into compliance in accordance with the

Proposal approved pursuant to paragraph 10, and under the supervision of FDA. Claimant shall destroy any article that has not been brought into compliance within ninety (90) calendar days of receiving written authority to commence implementing the Proposal, at its own expense and under the supervision of FDA, and shall file a notice with the court certifying that such articles have been destroyed.

14. Claimant shall not sell, ship, destroy, dispose of, or permit or cause another person to sell, ship, destroy, or dispose of, the condemned articles or any part of them in any manner contrary to the provisions of the Act, or other laws of the United States, or of any State or Territory (as defined in the Act), in which they are disposed of or sold. Except as provided in Paragraph 13, Claimant shall at no time, and under no circumstances whatsoever, directly or indirectly, cause or permit the shipment, sale, offer for sale, or other disposal of the condemned articles until:

A. FDA has had free access to the condemned articles in order to take any samples or make any tests or examinations that are deemed necessary; and

B. FDA has released, in writing, the condemned articles for shipment, sale, or other disposition. Such a release will be granted or denied within ten (10) calendar days of Claimant's request.

15. If Claimant breaches any condition of this Decree, or any subsequent Decree or order in this proceeding, Claimant shall immediately return legal custody of any of the condemned articles that have been released by FDA pursuant to paragraph 10(b) to the United States Marshal for this District, or otherwise dispose of them at its own expense pursuant to an order of this Court. In the event that return of any of the condemned articles becomes necessary pursuant to this paragraph, Claimant shall be responsible for all costs of storage and disposition

that are incurred by the United States.

16. If, within ninety (90) calendar days of the entry of this Decree, Claimant does not submit a Proposal as described in paragraph 10 above, Claimant, at its own expense and under the supervision of FDA, shall destroy such articles and make due return to this court regarding their disposition. Claimant shall reimburse the United States for any costs incurred pursuant to this paragraph, and shall pay such costs within thirty (30) calendar days of receiving an invoice from FDA.

17. The provisions in paragraphs 7-16 shall not apply to the following products:

A. Exhibit batches (also known as submission batches) that are the subject of bioequivalence testing studies for abbreviated new drug applications previously submitted or to be submitted to FDA for approval;

B. Retains;

C. Stability samples; and

D. Products that are the subject of pending or threatened litigation, which may be preserved in limited quantities for evidentiary purposes only, for so long as that need exists, but shall be destroyed under FDA supervision when that need no longer exists.

Claimant must identify any products that it intends to have covered in paragraph 17(A)-(D) to FDA and receive FDA's written approval that such products qualify for this paragraph. Claimant will isolate and hold all articles subject to this paragraph in a manner approved by FDA that ensures that any such articles in its possession, custody, and control are not introduced into interstate commerce.

18. Should Claimant fail to abide by and perform all the terms and conditions of paragraphs 5-16 above or any such further order or Decree as may be entered in this proceeding

relating to attempts to bring the condemned articles into compliance with the law, through reconditioning or destruction, then the bond or irrevocable standby letter of credit described in paragraph 7 above shall, on motion of the United States in this proceeding, be forfeited in its entirety or in such part as FDA, in its discretion, determines is appropriate to the United States of America and judgment entered thereon, and any condemned articles remaining in the custody of the United States Marshal shall be forfeited and disposed of pursuant to further order of this Court.

19. The United States Attorney for this District, upon being advised by an FDA representative that (a) all of the condemned articles have been brought into compliance with the Act and the requirements of this Decree, or destroyed in compliance with this Decree; and (b) that Claimant has paid all costs submitted to Claimant as of that date, will transmit such information to the clerk of this Court, whereupon the bond given in this proceeding shall be returned to the Claimant. The FDA shall notify the United States Attorney within five (5) business days after Claimant has completed (a) and (b).

20. Upon entry of this Decree, Claimant and each and all of its officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Decree, 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(a) by introducing or delivering for introduction into interstate commerce any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

B. Violates 21 U.S.C. § 331(k) by causing the adulteration of any drug within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drug is held for sale after shipment of one or more of its components in interstate commerce; and

C. Violates 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce, holding for sale after shipment into interstate commerce, manufacturing, processing, packing, labeling, holding, or distributing any new drug within the meaning of 21 U.S.C. § 321(p), unless and until:

(1) an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug; or

(2) an investigational new drug application filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect for such drug, and the use and distribution of such drug conforms strictly with the investigational new drug application.

21. Except as provided in subparagraph (K) below, upon entry of this Decree, Claimant and each and all of its officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly, manufacturing, processing, packing, labeling, holding, introduction, or delivery for introduction into interstate commerce at or from any of Claimant's facilities, of any drug, as defined by 21 U.S.C. § 321(g)(1), unless and until:

A. Claimant's methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in conformity with CGMP, 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211; and:

(1) Claimant establishes and documents management control over Quality Assurance ("QA") and Quality Control ("QC") for all of its facilities, including but not limited to Research and Development facilities and production facilities, to ensure continuous compliance with the Act, its implementing regulations, and this Decree. Responsibility for management control over QA and QC shall be vested in an individual who shall be authorized and responsible for all QA and QC functions at all of Claimant's facilities, including ensuring the establishment, implementation, and maintenance of a comprehensive written QA and QC program ("QA/QC program") to ensure that all drug products manufactured, processed, packed, held, and distributed by Claimant at all of Claimant's facilities have the safety, identity, strength, quality, purity, and potency that they purport or are represented to possess, and are in compliance with the provisions of this Decree;

(2) Claimant establishes and follows adequate written procedures for the storage and handling of components, including written procedures for executing the production and process control functions for "charge-in" of components to a batch;

(3) Claimant maintains accurate and complete inventory records of each component and reconciles the use of each lot of such component;

(4) Claimant establishes and follows adequate written procedures for the production and process control designed to assure that the drug products have the identity, strength, quality, and purity they are represented to possess;

(5) Claimant establishes and follows adequate written procedures describing the in-process controls and tests, or examinations of uniformity of drug Products;

(6) Claimant demonstrates that its equipment used in the

manufacturing, processing, packing, and holding of drug products is of an appropriate design to facilitate operations for its intended use;

(7) Claimant has established adequate procedures to thoroughly investigate any unexplained discrepancies and failures of batches to meet any of their specifications;

(8) Claimant has established and followed appropriate written procedures applicable to the quality control unit; and

(9) Claimant implements a quality system that rapidly identifies problems and adverse trends to ensure that emerging product quality problems are detected and corrective and preventive actions are implemented; and

(10) Claimant has established procedures to conduct follow-up to investigations of complaints; and

(11) Claimant establishes and follows adequate development and manufacturing process design procedures to control all significant variables (including material attributes and processing parameters) affecting in-process material and final drug product specifications and quality attributes; and

B. Claimant retains, at its own expense, an independent person or persons (the "CGMP expert"), who has no personal or financial relationship (other than the consulting agreement between the parties), with Claimant or with persons in the immediate families of the officers or employees of Claimant, and who by reason of background, training, education, and experience, is qualified to inspect Claimant's drug manufacturing facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Claimant shall notify FDA in writing of the identity and qualifications of the CGMP expert as

soon as it retains such expert; and

C. Claimant shall submit a protocol that identifies the work plan for the CGMP expert and the methodology that will be used by the CGMP expert (the "work plan") to ensure that Claimant's corrective actions are implemented and that the manufacturing, processing, packing, labeling, holding, and distribution of drugs is operated and will be continuously administered in conformity with CGMP. In addition to assuring general conformance with CGMP, the work plan must address, to FDA's satisfaction, the requirements in paragraph 21(A)(1)-(11). Within twenty (20) calendar days of receiving Claimant's work plan, FDA shall notify the Claimant in writing whether part or all of the work plan is approved. Claimant shall first obtain FDA's written approval of the work plan prior to the CGMP expert performing his or her inspection as set forth in paragraph 21(D)-(F); and

D. The CGMP expert shall perform a comprehensive inspection of Claimant's facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs. The CGMP expert shall determine whether Claimant's facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs are in compliance with CGMP; and

E. The CGMP expert shall evaluate whether Claimant has established and implemented a comprehensive written QA/QC program that is adequate to ensure continuous compliance with the Act, its implementing regulations, and this Decree. The CGMP expert, at a minimum, shall determine whether the QA/QC program:

(1) Satisfies all requirements in paragraph 21(A);

(2) Includes written standard operating procedures ("SOPs") specifying the responsibilities and procedures applicable to QA or QC personnel and that

establish mechanisms to ensure such SOPs are followed; and

(3) Establishes mechanisms to ensure that written SOPs are periodically re-evaluated so that they remain in continuous compliance with CGMP, and that the SOPs address all facets of CGMP and are reviewed and controlled by an independent QA unit; and

F. The CGMP expert certifies in writing to FDA that:

(1) He or she has inspected Claimant's facilities, methods, processes, and controls;

(2) Claimant has satisfied all requirements in paragraphs 21(A) and 21(E);

(3) All CGMP deviations brought to Claimant's attention since May 1, 2008, by FDA, the CGMP expert, or any other source, including but not limited to any experts hired prior to the entry of this Decree, have been corrected;

(4) Such facilities, methods, processes, and controls are in compliance with the requirements of CGMP; and

(5) As part of this certification, the CGMP expert shall include a complete and detailed report of the results of his or her inspection that includes all findings of deviations from CGMP, if any; and

G. Claimant submits to FDA for approval a written batch certification protocol ("certification protocol"), and shall not commence batch certification until FDA has first approved the certification protocol in writing. Within thirty (30) calendar days of receiving Claimant's certification protocol, FDA shall either reject or issue written approval of the certification protocol. Upon approval, Claimant's CGMP expert shall certify in writing that he or

she has witnessed the manufacture of three (3) consecutive batches of each drug and examined the manufacturing and control records, and the raw data associated with such records for each drug, and determined that the product meets the requirements of the certification protocol; and

H. Claimant reports to FDA in writing the actions it has taken to:

(1) Correct the CGMP deviations brought to Claimant's attention by FDA since May 1, 2008, the CGMP expert, and any other source including, but not limited to, any experts hired prior to the entry of this Decree; and

(2) Ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP.

Claimant may submit two (2) interim reports under this subparagraph 21(H), which shall include the CGMP expert certification described in subparagraph 21(F) in support of requests to begin manufacturing and distributing a particular product(s); and

I. Within thirty-five (35) calendar days following timely receipt of Claimant's first interim report under paragraph 21(H), FDA may, in its discretion and without prior notice, commence an inspection of Claimant's facilities to determine whether the requirements of this Decree have been met, and whether Claimant's facilities are operating in conformity with CGMP, the Act, its implementing regulations, and this Decree. For any subsequent interim report or a final report (if Claimant does not submit an interim report), FDA may conduct such an inspection within forty-five (45) calendar days following receipt of such reports; and

J. FDA notifies Claimant in writing that Claimant appears to be in compliance with the requirements set forth in paragraphs 21(A)-(I), which notification shall be

issued no later than forty-five (45) calendar days after conclusion of any inspection, or, if FDA does not inspect Claimant's facilities, within thirty-five (35) calendar days after receiving Claimant's report under paragraph 21(H). In no circumstance may FDA's silence be construed as a substitute for written notification.

K. Nothing in paragraph 21 shall preclude Claimant from manufacturing, processing, packing, and holding drug products for the sole purpose of conducting research and development, performing equipment qualification, performing supplier qualification, validation of drug manufacturing processes, method validation, or stability studies. Claimant shall maintain in a separate file at its facilities a written log of all lot numbers of drugs manufactured under this provision, and shall promptly make such log available to FDA upon request. None of the drugs produced under paragraph 21(K) may be distributed. Nothing in paragraph 21 shall preclude Claimant from distributing or introducing into interstate commerce finished product manufactured, packaged and labeled by third parties.

22. After Claimant has complied with paragraphs 20-21 and has provided the notifications pursuant to paragraph 21(H), Claimant shall retain an independent person or persons (the "auditor") to conduct an audit inspection of Claimant's drug manufacturing operations. After receipt of FDA notification pursuant to Paragraph 21(J), such audit inspections shall occur no less frequently than once every six (6) months for a period of no less than one (1) year; and annually thereafter for an additional period of four (4) years. . The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) with any of Claimant's officers or employees or their immediate families and may, if Claimant chooses, be the same person or persons described as the CGMP expert, as set forth in paragraph 21; and

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Claimant is in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations therefrom ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Claimant to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Claimant and FDA by courier service or overnight delivery service, no later than thirty (30) calendar days after the date the audit inspection(s) is completed. If an audit report identifies deviations from the Act, its implementing regulations, or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Claimant shall maintain the audit reports in separate files at its facility and shall promptly make the audit reports available to FDA upon request;

B. If an audit report contains information that indicates that the Claimant is not in compliance with CGMP, Claimant shall, within forty-five (45) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Claimant that a shorter time period is necessary. If, after receiving the audit report, Claimant believes that correction of the audit report observations will take longer than forty (40) calendar days, Claimant shall, within twenty (20) business days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule") and provide justification describing why the additional time is necessary. Before becoming effective, the correction schedule must be reviewed and approved by FDA in writing prior to implementation by Claimant. The FDA will issue a written decision, approving or disapproving the correction schedule, within ten (10) calendar days of the receipt of the corrections schedule. In no circumstance shall FDA's silence

be construed as a substitute for written approval. Claimant shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Claimant's receipt of an audit report, unless FDA notifies Claimant 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 Claimant to correct the audit report observations. Within ten (10) business days of beginning that review, Claimant shall report in writing to FDA the auditor's review and conclusions whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected; and

C. In addition to the foregoing audit reports, Claimant's auditor shall, with respect to each product that has been approved by FDA for distribution following the successful completion of batch certification described in paragraph 21(G) and resumption of manufacture and distribution under paragraph 21(J), report in writing to FDA on a quarterly basis, beginning with the date of entry of this Decree, whether the succeeding batches of such product(s) meet the protocol certification requirements. If any deadline in the Paragraph falls on a week-end or holiday, the deadline is continued to the next business day that is not a holiday.

23. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Claimant's facilities and 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 ready access to Claimant's facilities including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples of Claimant's finished and unfinished materials and products, containers, labeling, and other promotional material; and to examine and copy all

records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all of Claimant's drugs, including components thereof, in order to ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. 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 make inspections under the Act, 21 U.S.C. § 374.

24. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Claimant, the CGMP expert, the auditor, or any other information, that Claimant has failed to comply with any provision of this Decree, has violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Claimant in writing to take appropriate corrective actions, including, but not limited to, the following:

A. Cease all manufacturing, processing, packing, repacking, labeling, holding, and/or distributing any or all drug(s);

B. Recall, at Claimant's expense, any drug manufactured, processed, packaged, labeled, held, or distributed by Claimant that is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Issue a safety alert with respect to a drug manufactured, processed, packaged, labeled, held, or distributed by Claimant; and/or

F. Take any other corrective actions with respect to any drug manufactured, processed, packaged, labeled, held, or distributed by Claimant as FDA in its discretion, deems necessary to bring Claimant into compliance with this Decree, the Act, or its implementing regulations.

25. Unless a different time frame is specified by FDA in its order under paragraph 24, within five (5) business days after receiving an order pursuant to paragraph 24, Claimant shall notify FDA in writing either that (1) the Claimant is undertaking or has undertaken corrective action, in which event Claimant shall also describe the specific action taken or to be taken and the schedule for completing the action; or (2) the Claimant does not agree with FDA's order. If the Claimant notifies FDA that it does not agree with FDA's order, the Claimant shall explain in writing the basis for the disagreement; in so doing, the Claimant may also propose specific alternative actions and specific time frames for achieving FDA's objectives.

26. If the Claimant notifies FDA in writing that it does not agree with FDA's order, FDA will review the Claimant's notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate.

27. If FDA affirms or modifies its order, the Claimant shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable) and, if the Claimant so chooses, bring the matter before this Court on an expedited basis. All decisions specified in this Decree shall be vested in FDA's discretion and, if necessary, shall be reviewed by this Court pursuant to the terms set forth in paragraph 34 of this Decree.

28. The process and procedures set forth in paragraphs 25-27 shall not apply to any order issued pursuant to paragraph 24 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Claimant shall immediately and fully

comply with the terms of that order. Should Claimant seek to challenge any such order, it may petition this Court for relief.

29. Any cessation of operations or other action described in paragraph 24-28 shall continue until Claimant receives written notification from FDA that Claimant appears to be in compliance with this Decree, the Act, and its implementing regulations, and that Claimant may, therefore, resume operations. Upon Claimant's written request to resume operations, FDA shall determine within a reasonable time of receipt of the request whether Claimant appears to be in such compliance, and, if so, issue to Claimant a written notification permitting resumption of operations. The costs of FDA supervision, inspections, investigations, analyses, examinations, reviews, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraph 24, shall be borne by Claimant at the rates specified in paragraph 31 of this Decree.

30. The parties may at any time petition each other in writing to extend any deadline provided for herein; and, if the parties mutually agree to extend a deadline, such extension may be granted without seeking leave of Court.

31. Claimant shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate compliance with this Decree. The costs of such inspections shall be borne by Claimant at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $85.49 per hour and fraction thereof per representative for inspection work; $102.49 per hour or fraction thereof per representative for analytical or review work; $0.55 per mile for travel expenses 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-day, per-representative 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.

32. Within fifteen (15) business days after the date of entry of this Decree, Claimant must provide a list to FDA of all drugs that it has manufactured or distributed within one year before the date of entry of this Decree, or that it intends to manufacture or distribute within one year following the date of entry of this Decree, that do not have an approved new drug application or an approved abbreviated new drug application filed pursuant to 21 U.S.C. § 355.

33. The provision in paragraph 20(C) shall not apply to Choline Magnesium Trisalicylate. Within two (2) months of the date of entry of this decree, Claimant shall provide to FDA details of a plan for submitting an application for approval of Choline Magnesium Trisalicylate, or for establishing an exemption for that drug. Such plan shall not be implemented until approved in writing by FDA. If Claimant does not provide FDA with a plan for submitting an application for approval of, or a plan that establishes an exemption for, Choline Magnesium Trisalicylate that is acceptable to FDA within six (6) months after the date of entry of this decree, then FDA may, in its discretion, apply paragraph 20(C) to Choline Magnesium Trisalicylate.

34. Claimant shall abide by the decisions of FDA and its representatives, which shall be final. All decisions specified in this Decree shall be vested in FDA's discretion and, if necessary, shall be reviewed by this court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A).

Review by a court of any FDA decision rendered pursuant to this Decree shall be conducted without any discovery and shall be based exclusively upon the written record that was

before FDA at the time of the decision.

35. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Claimant shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

36. Claimant shall notify FDA, at the address specified in paragraph 39 below, at least ten (10) business days before any of the following events occur or within ten (10) calendar days after learning that any of the following events will occur if the event would affect Claimant's compliance obligations arising out of this Decree: any reorganization, relocation, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation of dissolution of subsidiaries, or any other change in its legal status.

37. Within ten (10) business days of the date of entry of this Decree, Claimant shall provide a copy of the Decree, by personal service, personal delivery via electronic mail with acknowledgment of receipt, return receipt email, or certified mail (restricted delivery, return receipt requested), to each and all of the following "Associated Persons": employees, directors, officers, agents, representatives, attorneys, successors, and assigns of Claimant, and any and all persons or entities in active concert or participation with any of them, including, but not limited to, all others involved in the manufacture of Claimant's products. In the event that Claimant becomes associated, at any time after the entry of this Decree, with new Associated Persons, Claimant shall within fifteen (15) calendar days of such association provide a copy of this Decree to such person(s) by electronic mail with acknowledgment of receipt, return receipt email, or certified mail (restricted delivery, return receipt requested). Within twenty (20) calendar days of the date of entry of this Decree, Claimant shall hold a general meeting or a

series of smaller meetings for all persons with responsibility for operations and manufacturing at any facility where Claimant holds articles of drug for introduction into interstate commerce, and upon the opening of any new such facility, at which it shall describe the terms and obligations of this Decree. Within thirty (30) calendar days of the date of entry of this Decree, Claimant shall furnish FDA with an affidavit of compliance with this paragraph (signed by a person with personal knowledge of the facts). Such affidavit should identify the names, addresses, and positions of all new Associated Persons that received a copy of the Decree.

38. Claimant shall post a copy of this Decree on a bulletin board in the employee common area of any distribution facility where Claimant holds articles of drug for introduction into interstate commerce, within ten (10) calendar days of the entry of this Decree or, if any new such facility is opened, within ten (10) calendar days of opening, and shall ensure that the Decree remains posted for a period of at least one year. Within thirty (30) calendar days of the date of entry of this Decree, Claimant shall provide to FDA an affidavit (signed by a person with personal knowledge of the facts) stating the fact and manner of its compliance with this paragraph.

39. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be marked "Consent Decree Correspondence" and shall be addressed to: District Director, FDA Detroit District Office, 300 River Place, Suite 5900, Detroit, MI, 48207.

40. If Claimant fails to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, Claimant shall pay to the United States of America: ten thousand dollars ($10,000) in liquidated damages for each day such violation continues; an additional sum of ten thousand dollars

($10,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree; and an additional sum equal to twice the retail value of each shipment of an adulterated drug, in liquidated damages for each such unlawful shipment. Any penalty imposed under this paragraph shall not exceed five million dollars ($5,000,000) in any calendar year. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

41. This Court retains jurisdiction to issue such further decrees and orders as may be necessary to the proper disposition of this proceeding.

ENTER:

United States District Judge

Dated this 29th day of September, 2009

Entry consented to:

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