RB

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

11 1745

UNITED STATES OF AMERICA,

Plaintiff,

v.

MCNEIL-PPC, INC., a corporation, and VERONICA CRUZ and HAKAN ERDEMIR, individuals,

Defendants.

Civil Action No._____

A TRUE COPY CERTIFIED FROM THE RECORD
DATED: MAR 10 2011
ATTEST: Steve Tomar
DEPUTY CLERK, UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against McNEIL-PPC, Inc., a New Jersey Corporation doing business in Pennsylvania, and elsewhere ("McNEIL-PPC"); Veronica Cruz, Vice President of Quality, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc., Fort Washington, Pennsylvania; and Hakan Erdemir, Vice President of Operations, Over-the-Counter Products, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (hereafter, collectively, "Defendants"), and Defendants having appeared and consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations in the Complaint, and disclaiming any liability in connection herewith, and before any testimony has been taken, and the United States of America, having consented to this Decree;

Veronica Cruz, an Individual Defendant, and McNEIL-PPC, having represented that Cruz assumed her position as Vice President of Quality for the McNeil Consumer Healthcare Division of McNEIL-PPC, Inc., on February 15, 2010, to help improve the quality systems and operations

of the Over-the-Counter business unit and resolve issues raised by the United States Food and Drug Administration ("FDA"); and Hakan Erdemir, an Individual Defendant, and McNEIL-PPC, having represented that Erdemir assumed the position of Vice President of North America Operations, Over-the-Counter Products, for the McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. on May 3, 2010, to help improve the quality systems and operations of the Over-the-Counter business unit and resolve issues raised by FDA;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. § 1345.

2. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c).

3. The Complaint alleges a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 ("the Act"), as follows:

A. The United States alleges that the Defendants violate 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, as defined by 21 U.S.C. § 321(g)(1) (hereinafter, "drug" or "drugs"), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that they have been manufactured, processed, packed, labeled, held, and distributed in violation of Current Good Manufacturing Practice ("CGMP") requirements, 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211; and

B. The United States alleges that the Defendants violate 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of articles of drug after shipment of one or more of their components in interstate commerce.

4. For the purposes of this Decree, "days" shall refer to calendar days unless otherwise stated. If any deadline under this Decree falls on a weekend or federal holiday, the deadline is continued to the next business day.

5. Within thirty (30) days of entry of this Decree, Defendants shall provide to FDA a schedule for destruction of all lots of drugs in McNEIL-PPC's possession, custody, and/or control that were manufactured at its facility in Fort Washington, Pennsylvania (the "Fort Washington Facility"), or the facilities it operates in Las Piedras, Puerto Rico (the "Las Piedras Facility") and Lancaster, Pennsylvania (the "Lancaster Facility"), and were recalled by McNEIL-PPC from December 2009 through the date of entry of this Decree. With respect to any additional recalled drugs manufactured at the Fort Washington, Las Piedras or Lancaster Facilities that subsequently come into McNEIL-PPC's possession, custody, and/or control after entry of this Decree, Defendants shall quarantine any such products, notify representatives of the United States Food and Drug Administration ("FDA") (no less frequently than quarterly) in writing of receipt of such drugs, and destroy all such products no later than ninety (90) days after their receipt. Defendants shall provide FDA ten (10) days advance written notice of any destruction to be performed under this Paragraph to afford FDA an opportunity to supervise the destruction. If FDA representatives supervise the destruction, McNEIL-PPC shall reimburse FDA for all costs associated with such supervision within thirty (30) days of receiving a bill of costs from FDA. If FDA chooses not to witness the destruction, Defendants shall provide FDA with a detailed written inventory of the products destroyed and the manner of their destruction within five (5) business days of such destruction. Defendants shall not dispose of any drugs in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969.

Notwithstanding the foregoing, Defendants are not required to destroy the following drugs (whether previously retained or returned pursuant to recall): (1) drugs that McNEIL-PPC retains for purposes of testing, including stability testing, or for conducting investigations (including investigation of complaints or adverse event reports); or (2) drugs retained for the purpose of pending or anticipated litigation. Any recalled drugs that are not destroyed pursuant to this provision will be quarantined and will not be distributed to market.

INJUNCTIVE PROVISIONS RELATING TO DEFENDANTS' FACILITY IN FORT WASHINGTON, PENNSYLVANIA

6. Upon entry of this Decree, Defendants and each and all of McNEIL-PPC's directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons or entities in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), 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 manufacturing, processing, packing, labeling, holding, and distributing drugs at or from the facility located in Fort Washington, Pennsylvania (the "Fort Washington Facility"), unless and until:

A. McNEIL-PPC's methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs at the Fort Washington Facility 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;

B. Defendants retain, at McNEIL-PPC's expense, an independent person or persons (the "CGMP expert"), who is without any personal or financial ties (other than the consulting agreement between the parties), to Defendants or their immediate families, and who, by reason of background, training, education, and experience, is qualified to inspect drug

manufacturing facilities to determine whether methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP expert as soon as they retain such expert. In the event Defendants have a need to replace such expert, they shall notify FDA in writing of any such successor within ten (10) business days after such replacement;

C. The CGMP expert begins a comprehensive inspection of the Fort Washington Facility to determine whether the methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute drugs at or from the facility are and, if properly maintained and implemented by Defendants, will continuously comply with the Act, CGMP, applicable federal regulations relating to the safety, identity, strength, quality, and purity of drugs, and this Decree (hereafter, collectively, "applicable laws and regulations"). In conducting this inspection, the CGMP expert shall review all CGMP deviations at the Fort Washington Facility brought to Defendants' attention in writing between October 2009 and the date of entry of this Decree by internal audit, FDA or any other regulatory authority (including, but not limited to, all Forms FDA-483 issued to McNEIL-PPC for the Fort Washington Facility), the CGMP expert, or by any other source. The CGMP expert shall also review all Forms FDA-483 issued to the Lancaster and Las Piedras Facilities since October 2009. The CGMP expert's inspection shall include, at a minimum, an evaluation as to whether, at the Fort Washington Facility:

(1) Defendants have adequate facilities and equipment;

(2) Defendants' equipment is appropriately designed for each of its intended uses and is adequately qualified and maintained;

(3) Defendants' manufacturing processes have been validated, and such validations establish and follow scientific product development and manufacturing process design

procedures that result in control of all significant variables (including component attributes and processing parameters) to ensure that in-process material and final drug products meet specifications throughout their product life cycle;

(4) Defendants have established and implemented a comprehensive, written quality assurance and quality control program ("QA/QC program") that is adequate to ensure continuous compliance with applicable laws and regulations. At a minimum, the CGMP expert shall determine whether the QA/QC program:

a. Operates in coordination with, and under appropriate oversight of, the applicable corporate-level QA/QC management within McNEIL-PPC's ultimate parent company, Johnson & Johnson;

b. Addresses all facets of compliance monitoring, trend analyses, and internal audit procedures, and ensures that McNEIL-PPC's Quality Control Unit, as defined by 21 C.F.R. § 210.3(b)(15), is adequately trained and staffed to evaluate CGMP compliance on an ongoing basis to prevent and promptly correct future deviations from applicable laws and regulations;

c. Ensures that personnel responsible for directing and conducting the manufacture and quality control of drugs are adequate in number and qualifications (education, training, and experience, or a combination thereof) to ensure compliance with applicable laws and regulations;

d. Includes written standard operating procedures ("SOPs") to ensure that Defendants: (i) thoroughly investigate and document in a timely manner any unexplained discrepancy or failure of a batch of drug product or any of its components to meet any of the product's or component's specifications; the investigations shall be extended to other

batches of the same product and other products that may have been associated with the specific failure or discrepancy; and (ii) take timely corrective actions for all products that fail to meet specifications;

e. Includes SOPs to ensure that the Defendants thoroughly investigate and document in a timely manner all drug complaints, returns, and adverse events, and all associated trends in these product quality deviations and/or problems, and that Defendants take all needed corrective actions in a timely manner;

f. Includes SOPs to ensure that: (i) McNEIL-PPC's appropriate QA/QC personnel are promptly notified in writing of deviations and/or problems at the Fort Washington Facility that could affect the safety, identity, strength, quality and purity of any drug; (ii) applicable corporate-level QA/QC management within McNEIL-PPC's ultimate parent company, Johnson & Johnson, participates in, audits or monitors the implementation and verification of corrective actions to prevent future occurrences of product quality deviations and; (iii) there are SOPs to ensure that such written SOPs are continuously followed;

g. Includes SOPs for the change control system to ensure that Defendants adequately qualify equipment and validate processes when changes (including, but not limited to, formulation changes, manufacturing changes, equipment changes, and procedural changes) are implemented. The SOPs shall, at a minimum, require Defendants to document: (i) how the qualification or validation study was conducted, including the test parameters, product characteristics, production equipment, and clear decision points for what constituted acceptable test results; (ii) whether the protocol for the equipment qualification or process validation study was adhered to during execution of the study and, if not, determine what deviations occurred and what effect(s) the deviations had on the results of the study; and (iii) Defendants' review of the

qualification or validation study results;

h. Includes procedures to ensure that SOPs are periodically re-evaluated so that they remain in continuous compliance with applicable laws and regulations and reflect McNEIL-PPC's current practices, and that these SOPs provide for all facets of compliance with CGMP to be reviewed and controlled by a Quality Control Unit that is independent from any other operating unit; and

i. Includes written SOPs specifying the responsibilities and procedures applicable to QA/QC personnel and establishing mechanisms to ensure such SOPs are followed;

(5) Defendants have established adequate management controls for the manufacture, processing, packing, labeling, holding, and distribution of drugs. The CGMP expert's review shall include, at a minimum, a description of Defendants' current organizational structure and the specific responsibilities of each of Defendants' organizational units that are involved in the manufacture, processing, packing, labeling, holding, and distribution of drugs;

(6) Defendants' employee training program and qualification practices ensure that: (a) each person engaged in the manufacture, processing, packing, or holding of a drug product has the education, training, and experience to enable that person to properly perform his or her assigned functions; (b) training is in the particular operations that the employee performs; (c) training is in CGMP (including the CGMP regulations set forth 21 C.F.R. Parts 210 and 211) as it relates to each employee's functions; and (d) training is conducted and monitored by qualified individuals on a continuing basis and with sufficient frequency to ensure that all employees remain familiar with their assigned functions and applicable CGMP requirements;

(7) Defendants have implemented a scientifically sound and appropriate system of laboratory controls that, at a minimum, includes specifications, standards, sampling plans, and test procedures necessary to ensure that components, product containers, closures, in-process materials, labeling, bulk drug substances, and finished drug products are in compliance with applicable laws and regulations;

(8) Defendants have implemented an effective building and facility control system that describes in sufficient detail cleaning and maintenance schedules, methods, equipment, and materials. The CGMP expert shall determine whether the system ensures, at a minimum, that: (a) materials are used in accordance with SOPs, and (b) SOPs are followed and documented;

(9) Defendants have processes in place to ensure the qualification of parties supplying materials, and the quality of purchased materials; and

(10) Defendants have processes in place to ensure that when one or more drug manufacturing, processing, packing, labeling, holding or distribution functions are contracted or outsourced to another party, responsibilities are defined for each party involved, periodic audits are performed, the contracted or outsourced site is appropriately monitored, and appropriate product and process information is promptly transferred from the Defendants to the other party;

D. The CGMP expert certifies in writing to FDA that: (1) the CGMP expert has inspected the Fort Washington Facility and Defendants' methods, facilities, processes, and controls as described in Paragraph 6.C; (2) all CGMP deviations at the Fort Washington Facility brought to Defendants' attention in writing between October 2009 and the date of entry of this Decree by internal audit, FDA or any other regulatory authority, the CGMP expert, or any other source have been corrected; and (3) Defendants' methods, facilities, processes, and controls used

to manufacture, process, pack, label, hold, and distribute drugs at or from the Fort Washington Facility are and, if properly maintained and implemented by Defendants, will continuously remain in conformity with applicable laws and regulations. As part of this certification, the CGMP expert shall include a full and complete written report with the detailed results of the CGMP expert's inspection and evaluation;

E. FDA representatives, if they choose, within sixty (60) business days of the expert's certification, begin an inspection of the Fort Washington Facility to determine whether the requirements of this Decree have been met, and whether Defendants are in conformity with applicable laws and regulations; and

F. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 6.A-D. If FDA elects not to begin an inspection pursuant to Paragraph 6.E, this notice will be issued within sixty (60) business days after receipt of the CGMP expert's certification under Paragraph 6.D.

G. Nothing in Paragraph 6 of this Decree shall preclude Defendants from manufacturing, processing, packing, and holding drug products at the Fort Washington Facility for the sole purpose of performing development activities, equipment qualification, validation of drug manufacturing processes, method validation, conducting investigations, or stability studies. Defendants shall maintain in a separate file at the Fort Washington Facility a log of all lot numbers of drugs manufactured under this provision, and shall promptly make such log available to FDA upon request. No drugs produced under this subparagraph may be commercially distributed.

H. The expert may, after reviewing the work performed before the date of entry of the Decree, rely on such work to satisfy the requirements of Paragraph 6. When such work

is relied upon, the expert shall identify with specificity the previous work upon which he or she relied.

PROVISIONS RELATING TO THE FACILITIES McNEIL-PPC OPERATES IN LAS PIEDRAS, PUERTO RICO AND LANCASTER, PENNSYLVANIA

7. The Las Piedras and Lancaster Facilities shall be subject to the following requirements:

A. Within ten (10) business days of the date of entry of this Decree, Defendants shall retain an independent CGMP expert to inspect each of the Las Piedras and Lancaster Facilities. The qualifications of the CGMP expert(s) shall be the same as those set forth in Paragraph 6.B. The CGMP expert(s) may, if Defendants choose, be the same person or persons described as the CGMP expert identified in Paragraph 6.B. The expert retained at the Lancaster Facility may be the same expert retained at the Las Piedras Facility. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP expert(s) as soon as they retain such expert(s). In the event Defendants have a need to replace such expert, they shall notify FDA in writing of any such successor within ten (10) business days after such replacement;

B. Within twenty (20) days after the date of entry of this Decree, Defendants shall cause the CGMP expert(s) to begin comprehensive inspections of the Las Piedras and Lancaster Facilities to ensure that the methods, facilities, and controls used to manufacture, process, pack, hold, and distribute drug products comply with applicable laws and regulations. In conducting each inspection, the CGMP expert(s) shall review all CGMP deviations at each facility brought to Defendants' attention in writing between October 2009 and the date of entry of this Decree by internal audit, FDA or any other regulatory authority (including, but not limited to, all Forms FDA-483 issued to McNEIL-PPC for the Fort Washington, Lancaster and Las Piedras

Facilities), the CGMP expert, or by any other source. The CGMP expert(s)' inspection shall include, at a minimum, a review of the CGMP concerns described in Paragraph 6.C(1)-(10).

C. The inspections of the Las Piedras and Lancaster Facilities shall be completed no later than one hundred fifty (150) days after the date of entry of this Decree.

D. Within twenty (20) days of the completion of each inspection, the CGMP expert(s) shall prepare a detailed written report of his/her inspection, which, at a minimum, addresses each of the CGMP concerns described in Paragraph 6.C(1)-(10) and whether all Form FDA 483 observations for the respective facility and other deviations brought to Defendants' attention in writing between October 2009 and the date of entry of this Decree by internal audit, FDA or any other regulatory authority, the CGMP expert, or any other source have been corrected have been corrected, and shall submit the inspection report concurrently to applicable corporate-level management at McNEIL-PPC's parent company, Johnson & Johnson, and FDA.

E. Within forty-five (45) days of receipt of each of the CGMP expert(s)' reports, Defendants shall submit a facility-specific written report ("workplan") for each facility to FDA detailing the specific actions Defendants have taken and/or will take to address the expert's observations and bring operations at the subject facility into compliance with applicable laws and regulations. The specific actions in each workplan shall be set forth in numbered steps and, where appropriate, the numbered steps may include subordinate lettered steps. Each workplan shall include a timetable with specific dates for completion of each numbered step and may include, where appropriate, interim dates for completion of subordinate lettered steps. Each workplan, including its proposed specific actions and timetable, shall be subject to FDA approval. Defendants shall ensure the implementation of the numbered steps in each workplan in accordance with the timetables approved by FDA.

F. As the numbered steps detailed in the workplans are completed, Defendants shall notify the applicable CGMP expert in writing. The applicable CGMP expert shall promptly inspect and verify whether such numbered steps have been completed to the CGMP expert's satisfaction and in accordance with the timetable approved by FDA. If the CGMP expert determines that a numbered step has not been completed to the CGMP expert's satisfaction, he/she shall promptly notify Defendants in writing. Beginning thirty (30) days after approval of each workplan by FDA, and thereafter quarterly, the CGMP expert at each facility shall submit to FDA a table that succinctly summarizes his/her findings regarding whether the numbered steps have been completed to the CGMP expert's satisfaction and in accordance with the numbered steps in the workplan timetable. In the event that FDA determines that an action that has been reported to be completed is inadequate, FDA will notify Defendants in writing, and Defendants shall take appropriate action in accordance with a timetable that is subject to approval by FDA.

G. When a CGMP expert determines that all of the actions identified in a workplan approved by FDA pursuant to Paragraph 7.E have been completed to the CGMP expert's satisfaction with respect to a particular facility, the CGMP expert shall provide Defendants and FDA with a written certification that all of the actions have been completed and that the methods, facilities, processes, and controls used to manufacture, process, pack, label, hold, and distribute drugs at or from the facility, based on the inspection conducted under Paragraph 7.B and on the satisfactory completion of the actions identified in the workplan identified under Paragraph 7.E, are and, if properly maintained and implemented by Defendants, will continuously remain in conformity with applicable laws and regulations.

H. Within forty-five (45) days of receipt of a certification, FDA may, in its discretion and without prior notice, begin an inspection of the facility and undertake such

additional examinations, reviews, and analyses (as provided in Paragraphs 13 and 14) as FDA deems appropriate to determine whether the facility is in conformity with applicable laws and regulations.

I. If FDA determines that the facility is not operating in conformity with applicable laws and regulations, FDA will notify Defendants of the deficiencies it observed and take any other action, if any, as FDA deems appropriate (*e.g.*, issuing an order pursuant to Paragraph 17 of this Decree).

J. Within thirty (30) days of receiving the notification from FDA under Paragraph 7.I, Defendants shall submit to FDA a written plan of actions Defendants propose to take and a timetable for correcting the deficiencies. The timetable shall be subject to FDA approval. Defendants shall promptly correct all deficiencies noted by FDA in accordance with the FDA-approved timetable, and cause the CGMP expert to reinspect and either (i) certify that the deficiencies have been corrected to ensure that the manufacturing facility is in conformity with applicable laws and regulations, or (ii) notify Defendants that the one or more deficiencies remain uncorrected. If one or more deficiencies have not been corrected, Defendants and the CGMP expert shall follow the procedures in Paragraph 7 until the CGMP expert issues the certification of compliance to Defendants and FDA.

K. The expert may, after reviewing the work performed before the date of entry of the Decree, rely on such work to satisfy the requirements of Paragraph 6. When such work is relied upon, the expert shall identify with specificity the previous work upon which he or she relied.

L. If FDA determines that the manufacturing, processing, packing, holding, and distribution of drugs at the facility appear to be in conformity with applicable laws and

regulations, FDA will notify Defendants in writing, as follows:

(1) If FDA conducts an inspection (or re-inspection) under Paragraphs 7.F and/or 7.H and finds that the manufacture, processing, packing, holding, and distribution of drugs at the facility appear to be in conformity with applicable laws and regulations, this notice will be issued within sixty (60) days after completion of such inspection.

(2) If FDA elects not to conduct an inspection pursuant to Paragraph 7.F or a reinspection pursuant to Paragraph 7.H, this notice will be issued within forty five (45) days after receipt of the CGMP expert's certification under Paragraph 7.G or 7.J.

M. Upon issuance of the notice with respect to any facility, FDA will not impose or continue any status (such as export certificate denials) based solely on the fact that the facilities at issue are subject to this Decree, and will consider issuance of export certificates in the ordinary course of business. Export certificates shall not be issued with respect to drugs manufactured before issuance of the notice set forth in Paragraph 7.L.

8. In the event that Defendants fail, as determined either by the CGMP expert or FDA, to satisfactorily complete one or more of the numbered steps in a workplan in accordance with the timetable approved by FDA pursuant to Paragraph 7.E, FDA shall have the sole and unreviewable discretion to order McNEIL-PPC to pay the United States Treasury as liquidated damages the sum of fifteen thousand dollars ($15,000.00) for each numbered step and for each day (*e.g.*, if two numbered steps remain uncorrected for two business days, the liquidated damages shall be $60,000.00), until the numbered steps are fully implemented and completed to FDA's satisfaction.

9. Unless otherwise provided for in the protocol, within fifteen (15) days of the date of entry of this Decree, Defendants shall implement the batch review protocol and sampling plans approved by FDA prior to entry of this Decree. The protocol and sampling plans may be amended

by written agreement between McNEIL-PPC and FDA without seeking leave of court.

10. No batch of finished product that is selected by the CGMP expert under the protocol and sampling plans described in Paragraph 9 shall be distributed from the Las Piedras and Lancaster Facilities unless and until (a) the CGMP expert has reviewed in-process, bulk, and finished product batch production records for that batch and has certified in writing to Defendants and applicable corporate-level management at McNEIL-PPC's ultimate parent company, Johnson & Johnson, that any deviations found did not adversely affect the safety, identity, strength, quality, and purity of the batch; and (b) McNEIL-PPC's QA director for the applicable facility has reviewed each certification and concurred with the CGMP expert's certification. The batch record review obligations under this Decree for each facility shall cease upon receipt of FDA's notification under Paragraph 7.L with respect to that facility.

11. Defendants shall, every sixty (60) days, provide supervisory corporate-level management at McNEIL-PPC's parent company, Johnson & Johnson, and FDA summary updates on the results of the batch record review completed pursuant to Paragraphs 9 and 10.

PERIODIC INSPECTIONS BY THE AUDITOR

12. Upon receiving each of the written notifications from FDA under Paragraph 6.F (for the Fort Washington Facility) or Paragraph 7.L (for the Las Piedras Facility and Lancaster Facilities), Defendants shall retain, at McNEIL-PPC's expense, an independent person or persons (the "auditor") to conduct audit inspections of the facility subject to the notification. The auditor(s) 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) to Defendants or their immediate families and may, if Defendants choose, be the same person or persons described as the CGMP expert(s), as set forth in Paragraphs 6 and 7. Defendants

shall notify FDA in writing as to the identity and qualifications of the auditor as soon as they retain such auditor.

A. Upon receiving a written notification from FDA under Paragraphs 6.F or 7.L, audit inspections for the facility identified in such notification shall begin no less frequently than once every six (6) months for a period of one (1) year, and annually thereafter for an additional four (4) year period.

B. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with applicable laws and regulations, and identifying in detail all 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 Defendants to correct all previous audit report observations for the subject facility. Audit reports shall also address, among other things, whether products have been appropriately validated and whether failure investigations are adequate in scope and depth (*e.g.*, include analysis of other batches of the same product and other products that may have been associated with the specific failure or discrepancy) and timeliness. The audit reports shall be delivered contemporaneously to Defendants and FDA, no later than fifteen (15) days after the date the audit inspection(s) is completed. If audit reports identify deviations at a facility 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 for that facility. In addition, Defendants shall maintain the audit reports in separate files at McNEIL-PPC's facilities and shall promptly make the audit reports available to FDA upon request.

C. If an audit report contains any adverse observations, Defendants shall, within thirty (30) days of receipt of the audit report, correct those observations, unless FDA

notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the audit report observations will take longer than thirty (30) days, Defendants shall, within ten (10) 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. The correction schedule shall be reviewed and approved by FDA in writing. 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.

D. Within forty-five (45) days of Defendants' receipt of an audit report, unless FDA notifies Defendants in writing that a shorter time period is necessary, or within the time period provided in a written correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within twenty (20) days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected. In the event that Defendants fail, as determined either by the auditor or FDA, to correct any audit report observations within thirty (30) days after Defendants receive an audit report, or after a shorter time period imposed in writing by FDA, or after the time period provided in a correction schedule approved by FDA, then FDA shall have the sole and unreviewable discretion to order McNEIL-PPC to pay to the United States Treasury as liquidated damages the sum of fifteen thousand dollars ($15,000.00) for each uncorrected observation for each day (*e.g.*, if two observations remain uncorrected for two business days, the liquidated damages shall be $60,000.00), until the observation is corrected to FDA's satisfaction.

GENERAL PROVISIONS

13. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Fort Washington, Las Piedras or Lancaster 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 Defendants' places of business 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 McNEIL-PPC'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 McNEIL-PPC's drugs and their components, including, all records and reports submitted pursuant to this Decree to applicable corporate-level management at McNEIL-PPC's ultimate parent company, Johnson & Johnson, 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.

14. McNEIL-PPC shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such activities shall be borne by McNEIL-PPC at the standard rates in effect at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: $87.57 per hour or fraction thereof per representative for inspection and investigative work; $104.96 per hour or fraction thereof per representative for

laboratory and analytical work; $0.51 per mile for travel expenses by automobile; the government rate or the equivalent for travel by air or other means; and the published government per diem rate 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.

15. Within fifteen (15) business days of the date of entry of this Decree, Defendants shall provide a copy of the Decree, by personal service, personal delivery via electronic mail (with acknowledgement of receipt or return receipt email), or certified mail (restricted delivery, return receipt requested), to each and all of the following "Associated Persons": (i) McNEIL-PPC's officers, directors, agents, representatives, attorneys, and to those employees and all other persons who are in active concert or participation with Defendants' manufacture, processing, packing, storage, or distribution of drugs at the Fort Washington, Las Piedras, and Lancaster Facilities; and (ii) all parties for whom McNEIL-PPC contract manufactures drugs. In the event that McNEIL-PPC becomes associated, at any time after the entry of this Decree, with new Associated Persons, Defendants shall within fifteen (15) days of such association provide a copy of this Decree to such person(s) by personal or electronic service or certified mail (restricted delivery, return receipt requested). McNEIL-PPC shall, on a quarterly basis, furnish FDA with an affidavit of compliance identifying the names, addresses, and positions of all new Associated Persons that received a copy of the Decree. Within twenty (20) days of the date of entry of this Decree, McNEIL-PPC shall post a copy of this Decree in the employee common areas in the Fort Washington, Las Piedras and Lancaster Facilities. Defendants shall ensure that the Decree remains posted in such employee common areas for no less than twelve (12) months. Within thirty (30) days of the date of entry of this Decree, 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 persons who received a copy of this Decree pursuant to this Paragraph.

16. McNEIL-PPC shall notify FDA, in writing at least fifteen (15) days before any change in ownership, character, or name of any of its businesses, including incorporation, reorganization, bankruptcy, assignment, sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the structure or identity of McNEIL-PPC, that may affect obligations arising out of this Decree. McNEIL-PPC shall provide a copy of this Decree to any prospective successor or assignee at least thirty (30) days prior to any sale or assignment. McNEIL-PPC shall furnish FDA with an affidavit of compliance with the previous sentence no later than fifteen (15) business days prior to such assignment or change in ownership.

17. 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 Defendants, the CGMP expert, or the auditor; or any other information, that Defendants have failed to comply with any provision of this Decree, have 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 (including, but not limited to, actions pertaining to the Fort Washington, Las Piedras, and Lancaster Facilities), FDA may, as and when it deems necessary, order Defendants in writing to take appropriate corrective actions with respect to the Fort Washington, Las Piedras, and Lancaster Facilities, or with respect to drugs manufactured at these facilities, 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 McNEIL-PPC's expense, any drug 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; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

18. The following process and procedures shall apply when FDA issues an order under Paragraph 17:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (i) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (ii) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement FDA's order, unless the Court stays, reverses, or modifies FDA's order. Any review of FDA's decision under this Paragraph shall be made pursuant to Paragraph 22.

D. The process and procedures set forth in Paragraphs 18.A-C shall not apply to any order issued pursuant to Paragraph 17 if such order states that, in FDA's judgment, the order raises significant public health concerns. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's order. Any review of FDA's decision under this Paragraph shall be made pursuant to Paragraph 22.

19. Any cessation of operations or other action described in Paragraph 17 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may, therefore, resume 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 17, shall be borne by McNEIL-PPC at the rates specified in Paragraph 14 of this Decree.

20. All FDA orders issued under this Decree shall be issued and signed by the District Director of the Philadelphia District Office. If Defendants fail 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, McNEIL-PPC shall pay to the United States of America: fifteen thousand dollars ($15,000.00) in liquidated damages for each day such violation continues, and an additional sum of fifteen thousand dollars ($15,000.00) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree (*e.g.*, if two violations occur for two business days, the liquidated damages shall be $60,000). In addition, should McNEIL-PPC distribute from the Fort Washington, Las Piedras, or Lancaster Facilities any drug (other than drugs permitted to be distributed under the provisions in Paragraphs 7-11) after entry of this Decree that violates the Act, its implementing regulations, and/or this Decree, it shall, in addition to the foregoing, also pay upon motion of the United States as liquidated damages a sum equal to two times the retail value of such drug(s). Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the power of the Court to impose, additional criminal or civil penalties or remedies based on conduct that may also be the basis for payment of such liquidated damages pursuant to this Paragraph. The remedies in this Paragraph shall not apply to Defendants' failure to satisfactorily complete any actions in the timetables approved by FDA pursuant to Paragraph 7.E or to Defendants' failure to correct audit observations pursuant to Paragraph 12, as payment for such failure is governed by Paragraphs 8 and 12.D of this Decree, respectively.

21. Payments of liquidated damages under this Decree shall not exceed ten million dollars ($10,000,000) per year.

22. 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) and shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

23. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be marked "Consent Decree Correspondence" and shall be addressed to the District Director, FDA Philadelphia District Office, Room 900 U.S. Customhouse, 2nd and Chestnut Streets, Philadelphia, PA 19106. All communications required to be sent to Defendants under this Decree shall be addressed to President, McNEIL-PPC, Inc., 7050 Camp Hill Road, Fort Washington, PA 19043.

24. Should Plaintiff bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants subject to the contempt action shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees and costs, travel expenses incurred by attorneys and witnesses, CGMP expert witness fees, investigational and analytical expenses, and court costs relating to such contempt proceedings.

25. This Decree resolves only those claims set forth in the Complaint. Defendants specifically state and agree that entry of this Decree does not preclude criminal charges; claims arising under the False Claims Act; common law claims and, if applicable, breach of contract; debarment; and/or exclusion in connection with any activity, including the conduct alleged in the Complaint filed with this Decree, relating to the activities of Defendants involving FDA-regulated products.

26. This Court retains jurisdiction over 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.

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

28. In the event McNEIL-PPC informs FDA in writing that any of the three facilities covered by this Decree has permanently ceased all operations (including manufacture, processing, packing, labeling and distribution of drugs), then McNEIL-PPC shall be enjoined from manufacturing, processing, packing, labeling and distributing drugs at or from that facility, and the requirements of Paragraphs 6 or 7 (as applicable) and 12 as to that facility shall cease.

29. If, and for so long as, an Individual Defendant ceases to have managerial responsibilities relating to the manufacture or distribution of OTC drugs at or from the Fort Washington, Las Piedras, or Lancaster Facilities, then that Individual Defendant shall not be subject to the terms of this Decree and may, upon prior written notice to FDA of thirty (30) calendar days, petition the Court to be released from this Decree, which Plaintiff will not oppose. However, such Individual Defendant shall continue to be liable under the Decree for such individual's act(s) or failure(s) to act under this Decree prior to the time he or she ceased to have such responsibilities on behalf of McNEIL-PPC, its ultimate parent company Johnson & Johnson, or any of its subsidiaries, franchises, affiliates, and/or "doing business as" entities.

30. If Defendants have maintained the Fort Washington, Las Piedras, and Lancaster Facilities in a state of continuous compliance with applicable laws and regulations and this Decree for at least sixty (60) months after satisfying all of their obligations under Paragraphs 6 and 7,

whichever obligations are satisfied last, Defendants may petition this Court for relief from this Decree, and the United States will not oppose such petition.

SO ORDERED, this _____ day of _____, 2011.

_____

UNITED STATES DISTRICT JUDGE

Entry consented to:

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