IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
v.	:	**CRIMINAL NO. 15-82**
MCNEIL-PPC, INC.	:	

UNITED STATES' GUILTY PLEA AND SENTENCING MEMORANDUM

I. INTRODUCTION

Defendant McNeil-PPC, Inc. ("McNeil") is charged by Information with one misdemeanor count of delivery for introduction into interstate commerce adulterated drugs, in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), specifically, 21 U.S.C. §§ 331(a), 333(a)(1) and 351(a)(2)(B). The charges arise from McNeil's failure to manufacture certain infants' and children's over-the-counter ("OTC") liquid drugs in conformance with current Good Manufacturing Practices ("cGMP"), rendering the drugs adulterated as a matter of law. The parties have entered into a plea agreement pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), and a guilty plea hearing has been scheduled for March 10, 2015 at 2:00 p.m.

Because the plea agreement is made pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), and the parties respectfully submit that a specific sentence is the appropriate disposition of the case, if that guilty plea is accepted by the Court, the parties have agreed to waive the presentence investigation and report pursuant to Federal Rule of Criminal Procedure 32(c)(1), and to jointly request, if acceptable to the Court, that the defendant be sentenced at the time that its guilty plea is entered. Accordingly, this memorandum addresses issues likely to arise at both guilty plea and sentencing hearings.

The plea agreement resolves a significant criminal investigation into McNeil's manufacturing practices for the production of several infants' and children's OTC liquid drugs in the United States. The essence of the charge is that McNeil did not manufacture certain infants' and children's OTC liquid drugs in conformance with cGMP, rendering the drugs adulterated as a matter of law. In addition, the company remains under a Consent Decree of Permanent Injunction entered in 2011 (E.D. Pa. 11-cv-01745). The proposed criminal resolution is sufficient to punish McNeil for its past failures and to deter McNeil from violating the FDCA in the future. The permanent injunction will help to ensure McNeil manufactures product in compliance with cGMP going forward.

The 2011 permanent injunction – which has been in effect for most of the criminal investigation – applies to all of McNeil's facilities in the United States. Under the terms of the permanent injunction, McNeil agreed to close its Fort Washington, Pennsylvania facility for remediation, and the plant has yet to reopen. McNeil's other facilities in the United States continue to operate, but under the terms of the permanent injunction. McNeil is currently working to bring its Fort Washington facility into cGMP compliance and expects to reopen the facility after it fulfills all of its obligations for that plant and receives notification from the U.S. Food and Drug Administration ("FDA") pursuant to the permanent injunction.

II. THE PLEA AGREEMENT

The full terms of the plea agreement are set forth in the plea agreement itself, which is attached as Exhibit A. The original will be filed at the time of the guilty plea hearing. The essential terms are as follows:

- McNeil, by its undersigned representatives and attorneys, and pursuant to the power granted by its Board of Directors, agrees to plead guilty to a one-count

Information charging a misdemeanor violation of the FDCA, 21 U.S.C. §§ 331(a), 333(a)(1), 351(a)(2)(B). The charge arises from McNeil's violation of cGMP in the manufacture of infants' and children's OTC liquid medicines, which renders them adulterated as a matter of law without any showing of an actual defect. McNeil also agrees not to contest forfeiture as set forth in the agreement. (Plea Agreement, par. 1).

- The parties entered into this plea agreement under Fed.R.Crim.P. 11(c)(1)(C), with a stipulated sentence. (Plea Agreement, par. 2).

- The agreed-upon sentence is payment of $25,000,000 ($20,000,000 as the criminal fine and $5,000,000 as the criminal forfeiture), payable within 10 business days of sentencing, plus the special assessment of $125. In light of the Consent Decree of Permanent Injunction against McNeil (E.D. Pa. 11-cv-01745), the parties agree that McNeil will not be placed on probation. (Plea Agreement, par. 2).

- The parties stipulate to the following facts and basis for the plea, criminal fine and forfeiture. (Plea Agreement, par. 6). At all times relevant to this matter:

  (1) McNeil manufactured infants' and children's liquid OTC drugs at McNeil's facility in Fort Washington, Pennsylvania. These OTC drugs were drugs within the meaning of 21 U.S.C. § 321(g)(1).

  (2) A drug was deemed adulterated within the meaning of FDCA, 21 U.S.C. § 351(a)(2)(B), if the methods used in, or the facilities and controls used for, the manufacture, processing, packing, labeling, holding, and distribution of drugs and components were not in conformance with cGMP regulations for drugs. 21 C.F.R. Parts 210 and 211. Drugs not manufactured, processed, packed, or held in conformance with cGMP regulations were deemed adulterated as a matter of federal law, without any showing of actual defect. The FDCA prohibited the introduction or delivery for introduction into interstate commerce of any drug that was so deemed adulterated. 21 U.S.C. § 331(a). Implementing regulations under the FDCA further defined cGMP for drugs. Specifically, under 21 C.F.R. § 211.100(a) & (b): "There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. . . . Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified."

  (3) In certain instances, from in or about May 2009 to in or about April 2010, McNeil's written production and process control procedures were not followed in the execution of production and process control functions

(as required by 21 C.F.R § 211.100). Specifically, McNeil's Standard Operating Procedure ("SOP") required a Corrective Action Prevention Action ("CAPA") plan to be initiated when systemic good manufacturing practice issues or significant trends had been identified associated with nonconformance events, consumer complaints, manufacturing events and significant trends. McNeil's SOP defined a CAPA as a process for ensuring that identified corrective and preventive actions were verified for effectiveness.

(4) No CAPA was initiated for multiple batches from in or about May 2009 to in or about April 2010 where foreign material, particulate matter and/or contamination were observed. Failure to initiate a CAPA did not comply with McNeil's SOP, and thus, did not comply with cGMP for drugs. Therefore, certain drugs manufactured, processed, packed, or held not in conformance with cGMP requirements by McNeil were deemed adulterated as a matter of federal law, without any showing of actual defect.

(5) McNeil delivered for introduction into interstate commerce certain batches of OTC drugs that were deemed adulterated as a matter of federal law in that such drugs were not manufactured, processed, packed, or held in conformance with the cGMP requirements as set forth in subsections 2 through 4.

(6) On or about August 24, 2009, McNeil delivered for introduction into interstate commerce a batch of an OTC drug that was deemed adulterated as a matter of federal law in that the drugs were not manufactured, processed, packed, or held in conformance with the cGMP requirements as set forth in subsections 2 through 4.

- The Plea Agreement includes a non-prosecution clause for conduct which (A) falls within the scope of the criminal investigation in the Eastern District of Pennsylvania relating to the manufacture and distribution of McNeil's OTC products, FDA's inspections of McNeil's manufacturing facilities, and the reporting of information to the government; or (B) was known to the United States Attorney's Office for the Eastern District of Pennsylvania or the Consumer Protection Branch of the Department of Justice as of the date of the execution of the plea agreement, and which concerned the manufacture and distribution of McNeil's OTC products, FDA inspections of McNeil's manufacturing facilities, and the reporting of information to the government. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the Eastern District of Pennsylvania, the Consumer Protection Branch of the Department of Justice, and the United States Attorney's Offices for each of the other 93 judicial districts of the United States. The non-prosecution provisions are also binding on the Criminal Division of the United States Department of Justice, except that the investigation of McNeil and its affiliates,

divisions, and subsidiaries, if any, being conducted by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the manufacturing of McNeil's products for foreign customers is specifically excluded from the non-prosecution provisions and release. (Plea Agreement, par. 7).

- The Plea Agreement contains an appellate waiver. There can be no appeal if the Court enters the plea under Rule 11(c)(1)(C). (Plea Agreement, par. 11).

- If acceptable to the Court, the parties agree to waive the presentence investigation and report pursuant to Fed.R.Crim.P. 32(c)(1), and ask that McNeil be sentenced at the time the guilty plea is entered. (Plea Agreement, par. 15).

III. THE CRIMINAL CHARGE

The Information filed in this case charges McNeil with one count of delivery for introduction into interstate commerce drugs that were deemed adulterated because they were not manufactured in conformity with cGMP under the FDCA, 21 U.S.C. §§ 331(a), 333(a)(1) and 351(a)(2)(B).

As the Information explains, the FDCA governs the approval, manufacture, and distribution of drugs to ensure that they are safe and effective for their intended uses in humans. The FDCA prohibits causing the introduction or delivery for introduction into interstate commerce of any drug that is adulterated. A drug is deemed adulterated, without any showing of actual defect, if the methods used in, or the facilities and controls used for, the manufacture, processing, packing, labeling, holding, and distribution of drugs and components are not in conformity with cGMP for drugs.

The cGMP regulations, set forth in 21 C.F.R. Parts 210 and 211, contain "the minimum current good manufacturing practice for methods to be used in, and the facilities and controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the [FDCA] as to safety, and has the identity and strength and meets the quality and purity characteristics that it

purports or is represented to possess." 21 C.F.R. § 210.1(a). Following cGMP helps prevent contamination, mix-ups, deviations, failures, and errors in the manufacturing process. These regulations require the manufacturer to set product specifications for such factors as potency, stability and purity, and to put in place a quality system that ensures those specifications are met. The cGMP regulations require the manufacturer to meet its own standards and specifications.

The relevant cGMP regulations in this case require written procedures for production and process control that are designed to assure that the drug products have the identity, strength, quality, and purity that they purport or are represented to possess. A manufacturer must follow the written procedures in executing the various production and process control functions, and must document the procedures which were followed at the time they were performed. Any deviation from the written procedures must be recorded and justified. As part of these procedures, the manufacturer should have a system for implementing corrective actions and preventive actions resulting from its investigation of any problem that arises in the manufacturing process. Problems may include complaints, product rejections, nonconformances, deviations, and recalls, and issues that are discovered in internal audits, regulatory inspections, and trends from process performance and product quality monitoring.

A CAPA plan can be adapted to the specifics of the situation, and should result in an investigation that is commensurate with the level of risk and that determines a root cause for the problem and should result in improvements. A proper and cGMP-compliant CAPA plan is more than a narrowly-focused investigation or a one-time correction to a specific event. A CAPA plan should determine root causes in order to prevent the

problem from reoccurring and to provide assurance that the drugs manufactured after the CAPA have the identity, strength, quality, and purity that they purport or that the manufacturer represents them to possess.

The Information alleges that McNeil's infants' and children's OTC liquid drugs were deemed adulterated because they were not manufactured in conformity with cGMP. Specifically, McNeil failed to implement a CAPA plan to address contaminants repeatedly found in the infants' and children's OTC liquid drugs manufactured at its Fort Washington, Pennsylvania plant from May 2009 until April 2010. As the Information explains, McNeil learned of the problem in May 2009 when a consumer returned a bottle of liquid Infants' Tylenol because it contained "black specks." McNeil later identified the material as including nickel/chromium-rich inclusions, which were not intended ingredients in this drug.

Part of the machinery used to manufacture this product, and many other infants' and children's OTC liquid drugs at McNeil's Fort Washington plant, is made from Waukesha 88, a composite metal that is mostly nickel, but also includes tin, iron, bismuth and chromium. During the May 2009 incident, McNeil failed to link the metal particles to McNeil's manufacturing equipment. McNeil failed to initiate or complete a CAPA plan to correct or prevent repetition of this incident.

As the Information alleges, McNeil itself found particles in OTC liquid drugs during production at the Fort Washington plant on January 19, 2010; March 16, 2010; and April 8, 2010. Each time, the particles contained metals that were not intended ingredients for the OTC liquid drugs, but were consistent with the Waukesha 88 material present in the equipment that manufactures the liquid drugs. During the January and

March incidents, McNeil again failed to initiate or complete a CAPA plan to correct or prevent repetition of the incidents. After the April 8, 2010, incident, McNeil began to connect the April and January incidents, but it continued to manufacture infants' and children's OTC liquid drugs on the liquid lines. Finally, McNeil stopped production on one of its liquid lines on or about April 13, 2010, when it found discolored OTC liquid drug product on the base of a liquid filler machine during production of Infants' Tylenol. McNeil eventually determined that the OTC liquid drug product was leaking from a part of the machine, and lab testing confirmed that the liquid contained various metals matching the metals in Waukesha 88 present in the liquid line manufacturing equipment. None of these metals were intended ingredients in this OTC liquid drug.

During an FDA inspection of the facility in April 2010, FDA determined that McNeil lacked a CAPA plan covering the particles and other foreign material found in the infants' and children's OTC liquid drugs. At the end of the FDA inspection, FDA issued a detailed List of Inspectional Observations. FDA found that McNeil had failed to comply with cGMP requirements when, despite McNeil's Standard Operating Procedures requirement for CAPA, McNeil failed to initiate a CAPA plan for multiple batches of infants' and children's OTC liquid drugs from in or around May 2009 to in or around April 2010 where foreign material, particulate matter and/or contamination were observed.

On April 30, 2010, in consultation with FDA, McNeil recalled all lots of certain unexpired infants' and children's OTC drugs manufactured at the Fort Washington plant. The recall included Infants' and Children's Tylenol and Infants' and Children's Motrin.

McNeil issued a press release that day stating that some of the recalled OTC drugs "may contain tiny particles."

The Information charges that from in or around May 2009 to in or around April 2010, McNeil delivered for introduction into interstate commerce OTC liquid drugs that were deemed adulterated because they were not manufactured, processed, packed, or held in conformity with cGMP. This is the charge to which McNeil is pleading guilty.

IV. ESSENTIAL ELEMENTS OF THE OFFENSE

A. Adulteration

The Information charges one count of delivering for introduction into interstate commerce OTC liquid drugs that were deemed adulterated because they were manufactured, processed, packed, or held not in conformance with cGMP, in violation of the FDCA, 21 U.S.C. §§ 331(a), 333(a)(1) and 351(a)(2)(B).

Section 331 of Title 21, United States Code, lists prohibited acts, including "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a).

Under 21 U.S.C. § 351, a drug is "adulterated" under several circumstances, including (as relevant here):

> A drug or device shall be deemed to be adulterated if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B).

In order to prove adulteration under a cGMP theory, the Government must establish the following elements beyond a reasonable doubt:

(1) McNeil introduced or delivered for introduction into interstate commerce a drug;

(2) that was adulterated at the time of the introduction or delivery for introduction into interstate commerce.

Under 21 U.S.C. § 333(a)(1), this crime is punishable as a misdemeanor.

B. Forfeiture

Under federal forfeiture law, the Government can pursue criminal forfeiture in any case where the defendant is charged with a violation of an Act of Congress for which the civil or criminal forfeiture of property is authorized. A violation of the FDCA allows for the seizure and possible forfeiture of adulterated drugs under 21 U.S.C. § 334, which allows proceedings on libel of information, for condemnation, against drugs that are adulterated so that the Government can seize, destroy or sell them. Accordingly, because civil seizure and possible forfeiture is authorized under the FDCA, criminal forfeiture is authorized as well. As the adulterated drugs are no longer available for forfeiture, the Government can seek substitute assets. See 28 U.S.C. §2461(c) (the procedures set forth in 21 U.S.C. § 853 apply to this criminal forfeiture); 21 U.S.C. § 853(p) (allowing the forfeiture of substitute assets if the items subject to forfeiture are no longer available).

V. MAXIMUM PENALTIES

The maximum penalty for this offense is a fine of $200,000 (under 18 U.S.C. § 3571(c)(5)), or twice the gross gain or gross loss, whichever is greater (18 U.S.C. § 3571(d)); a special assessment of $125 (18 U.S.C. § 3013(a)(1)(B)(iii)); and a five-year term of Court supervision (18 U.S.C. § 3561(c)(2)); in addition forfeiture may be ordered.

VI. FACTUAL BASIS FOR THE PLEA

In the plea agreement, the parties have stipulated to a factual basis sufficient to support the entry of this plea. (Plea Agreement, par. 6). If this case were to proceed to trial, the Government would prove these facts beyond a reasonable doubt.

VII. THE SENTENCING CONSIDERATIONS

The agreed-upon sentence takes into account McNeil's conduct under the fine provisions of 18 U.S.C. § 3572, as well as the considerations set forth in 18 U.S.C. § 3553 and the United States Sentencing Guidelines. The criminal fine and forfeiture is based on a percentage of the sales of specific infants' and children's OTC liquid medicines between May 2009 and April 2010. These OTC drugs, such as liquid Children's Tylenol from Fort Washington, should have been subject to a CAPA plan but they were not. During the 2010 Inspection, FDA asked McNeil for a comprehensive list of all non-conformances for particles, along with the associated OTC drug batches, that had occurred since the 2009 Inspection. This document revealed 30 batches of non-conforming OTC liquid drugs, including Infants' Tylenol, Children's Tylenol, and Children's Motrin. FDA then asked McNeil for the CAPA plan covering the particles and foreign material found in the OTC drugs. A McNeil employee confirmed that McNeil did not have such a CAPA plan. Between May 2009 and April 2010, batches of Infants' Tylenol, Children's Tylenol, and Children's Motrin were distributed and sold by McNeil, despite the fact that McNeil did not institute a CAPA plan. McNeil's proposed sentence reflects the breadth and length of the company's failure to follow cGMP in the manufacturing of liquid infants' and children's medicines. This agreed-upon sentence

falls within the statutory maximum set forth in 18 U.S.C. § 3571(d) (twice the gross gain or loss).

The proposed criminal resolution accomplishes the goals of sentencing under 18 U.S.C. § 3553, considering the nature and circumstances of the offense and the history and characteristics of the defendant. As Joshua M Sharfstein, M.D., Principal Deputy Commissioner of the FDA observed in his May 27, 2010 testimony before Congress about McNeil's manufacturing practices, "[a]lthough the public health risk from these quality problems is low, these problems should never have occurred, and the cGMP failures at the facility that caused them were unacceptable." This sentence promotes respect for the law, specifically, respect for the cGMP regulations that keep American consumers safe when they open their medicine cabinets. This sentence will deter McNeil and others from violating cGMP.

VIII. CONCLUSION

For the foregoing reasons, the United States respectfully recommends that the Court sentence McNeil to a criminal fine in the amount of $20,000,000, impose asset forfeiture in the amount of $5,000,000, and require a special assessment of $125.

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DATE: 3/9/2015

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
v.	:	**CRIMINAL NO.**
MCNEIL-PPC, INC.	:	

GUILTY PLEA AGREEMENT

Under Federal Rule of Criminal Procedure 11(c)(1)(C), the government, the defendant McNeil-PPC, INC. (hereinafter "McNeil"), and McNeil's counsel enter into the following guilty plea agreement. Any reference to the United States or the government in this agreement shall mean the Office of the United States Attorney for the Eastern District of Pennsylvania and the Consumer Protection Branch of the Department of Justice.

1. McNeil agrees to plead guilty to Count One of an Information charging it with the delivery for introduction into interstate commerce of drugs that were deemed adulterated, a misdemeanor, in violation of Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a), 333(a)(1) and 351(a)(2)(B), and not to contest forfeiture as set forth in the notice of forfeiture seeking forfeiture of $5,000,000 in substitute assets, in lieu of the drugs which were deemed adulterated and are no longer available, all arising from McNeil's delivery for introduction into interstate commerce of certain over-the counter ("OTC") drugs which were deemed adulterated as a matter of federal law in the United States. McNeil further acknowledges its waiver of rights, as set forth in Exhibit A to this agreement.

2. The parties agree that this plea agreement is made pursuant to Fed.R.Crim.P. 11(c)(1)(C) and that the following specific sentence is the appropriate disposition of this case. Taking into consideration the factors set forth in 18 U.S.C. §§ 3553(a) and 3572, the agreed upon

sentence is as follows:

A. McNeil agrees to pay the special assessment in the amount of $125 on the date of sentencing.

B. McNeil agrees to pay $25,000,000 to resolve this Information, of which $20,000,000 will be applied as a criminal fine, and $5,000,000 will be applied as substitute assets to satisfy the forfeiture obligation described in paragraph 2(C) below. McNeil will pay these amounts within 10 business days of the date of sentencing. McNeil and the government agree that this fine and forfeiture represent a fair and just resolution of all issues associated with the fine and forfeiture calculations.

C. McNeil agrees that as a result of its acts or omissions, the forfeitable property, that is the drugs deemed adulterated, are no longer available for forfeiture as the drugs cannot be located or have been transferred, sold or deposited with a third party, or otherwise disposed of, within the meaning of federal law. As a result, McNeil agrees to the entry and satisfaction of a judgment and preliminary order of forfeiture on the date of the guilty plea, forfeiting to the United States the sum of $5,000,000 as substitute assets for the pertinent drugs. McNeil agrees that, within 10 business days of the date of sentencing, McNeil will make payment to the United States, by means of a wire transfer to the United States Marshal Service or check payable to same, in the amount of $5,000,000, this amount representing substitute assets of the offense for which it is pleading guilty, subject to forfeiture in full satisfaction of the judgment and preliminary order of forfeiture.

D. In light of the Consent Decree of Permanent Injunction (E.D. Pa. 11-cv-01745), McNeil will not be placed on probation.

3. McNeil waives any and all defenses and objections in this matter which might be available under the Double Jeopardy and Excessive Fines clauses of the Eighth Amendment. The parties agree that to avoid unduly complicating and prolonging the sentencing process, the appropriate disposition of this case does not include a restitution order.

4. McNeil waives any claim under the Hyde Amendment, 18 U.S.C. § 3006A (Statutory Note), for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.

5. McNeil understands, agrees and has had explained to it by counsel that the Court may impose the following statutory maximum sentence: a fine of $200,000, or twice the gross gain or gross loss, whichever is greater; a special assessment of $125; restitution as ordered by the Court; and a five-year term of Court supervision; in addition, forfeiture may be ordered. McNeil further understands that the terms and conditions of any Court supervision may be changed, and extended, by the Court if McNeil violates any of the terms and conditions of that supervision.

6. With respect to McNeil's conduct, the parties stipulate to the following facts and basis for the plea, criminal fine and forfeiture. At all times relevant to this matter:

A. McNeil manufactured infant's and children's liquid OTC drugs at McNeil's facility in Fort Washington, Pennsylvania. These OTC drugs were drugs within the meaning of 21 U.S.C. § 321(g)(1).

B. A drug was deemed adulterated within the meaning of FDCA, 21 U.S.C. § 351(a)(2)(B), if the methods used in, or the facilities and controls used for, the manufacture, processing, packing, labeling, holding, and distribution of drugs and components were not in conformance with Current Good Manufacturing Practice ("CGMP") regulations for drugs. 21 C.F.R. Parts 210 and 211. Drugs not manufactured, processed, packed, or held in conformance with CGMP regulations were deemed adulterated as a matter of federal law, without any showing of actual defect. The FDCA prohibited the introduction or delivery for introduction into interstate commerce of any drug that was so deemed adulterated. 21 U.S.C. § 331(a). Implementing regulations under the FDCA further defined

CGMP for drugs. Specifically, under 21 C.F.R. § 211.100(a) & (b): "There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. . . . Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified."

C. In certain instances, from in or about May 2009 to in or about April 2010, McNeil's written production and process control procedures were not followed in the execution of production and process control functions (as required by 21 C.F.R § 211.100). Specifically, McNeil's Standard Operating Procedure ("SOP") required a Corrective Action Prevention Action plan ("CAPA") to be initiated when systemic good manufacturing practice issues or significant trends had been identified associated with nonconformance events, consumer complaints, manufacturing events and significant trends. McNeil's SOP defined a CAPA as a process for ensuring that identified corrective and preventive actions were verified for effectiveness.

D. No CAPA was initiated for multiple batches from in or about May 2009 to in or about April 2010 where foreign material, particulate matter and/or contamination were observed. Failure to initiate a CAPA did not comply with McNeil's SOP, and thus, did not comply with CGMP for drugs. Therefore, certain drugs manufactured, processed, packed, or held not in conformance with CGMP requirements by McNeil were deemed adulterated as a matter of federal law, without any showing of actual defect.

E. McNeil delivered for introduction into interstate commerce certain batches of OTC drugs that were deemed adulterated as a matter of federal law in that such drugs were not manufactured, processed, packed, or held in conformance with the CGMP requirements as set forth in subsections 6(B) through 6(D).

F. On or about August 24, 2009, McNeil delivered for introduction into

interstate commerce a batch of an OTC drug that was deemed adulterated as a matter of federal law in that the drugs were not manufactured, processed, packed, or held in conformance with the CGMP requirements as set forth in subsections 6(B) through 6(D).

7. Except as provided herein, the United States agrees that, other than the charges in the Information in this case, it will not bring any other criminal charges against McNeil, its present and former parents, affiliates, divisions, and subsidiaries; their predecessors, successors and assigns for conduct which (A) falls within the scope of the criminal investigation in the Eastern District of Pennsylvania relating to the manufacture and distribution of McNeil's OTC's products, the U.S. Food and Drug Administration's ("FDA") inspections of McNeil's manufacturing facilities, and the reporting of information to the government; or (B) was known to the United States Attorney's Office for the Eastern District of Pennsylvania or the Consumer Protection Branch of the Department of Justice as of the date of the execution of this plea agreement, and which concerned the manufacture and distribution of McNeil's OTC's products, the U.S. FDA inspections of McNeil's manufacturing facilities, and the reporting of information to the government. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the Eastern District of Pennsylvania, the Consumer Protection Branch of the Department of Justice, and the United States Attorney's Offices for each of the other 93 judicial districts of the United States. The non-prosecution provisions are also binding on the Criminal Division of the United States Department of Justice, except that the investigation of McNeil and its affiliates, divisions, and subsidiaries, if any, being conducted by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the manufacturing of McNeil's products for foreign customers is specifically excluded from the non-prosecution provisions and release provided by this paragraph and agreement. Attached as Exhibit B is a copy of the letter to the United States Attorney's Office for the Eastern District of Pennsylvania from the Office of the Assistant

Attorney General, Criminal Division, Department of Justice, authorizing this agreement.

8. McNeil understands that this guilty plea agreement does not bind any other government agency, or any component of the Department of Justice except as specified in paragraph 7 of this guilty plea agreement. Further, McNeil understands that the United States takes no position as to the proper tax treatment of any of the payments made by McNeil pursuant to this plea agreement.

9. McNeil agrees to waive the statute of limitations, and any other time-related defense, to the charge to which it is agreeing to plead guilty under this plea agreement, provided that the guilty plea is accepted by the Court.

10. McNeil understands and agrees that, should it withdraw its plea or if McNeil's guilty plea is not accepted by the Court for whatever reason, McNeil may thereafter be prosecuted for any criminal violation of which the United States has knowledge arising out of this investigation, notwithstanding the expiration of any applicable statute of limitations between the time period when McNeil signed this plea agreement and either McNeil's withdrawal of its plea or the Court's rejection of its plea. In that event, McNeil agrees that it will not raise the expiration of any statute of limitations as a defense to any such prosecution, except to the extent that the statute of limitations would have been a defense pursuant to the terms of any Tolling Agreement between the parties, and this paragraph.

11. In exchange for the undertakings made by the government in entering this plea agreement, McNeil voluntarily and expressly waives all rights to appeal or collaterally attack the defendant's conviction, sentence, or any other matter relating to this prosecution, whether such a right to appeal or collateral attack arises under 18 U.S.C. § 3742, 28 U.S.C. § 1291, 28 U.S.C. § 2255, or any other provision of law. This waiver is not intended to bar the assertion of constitutional claims that the relevant case law holds cannot be waived.

12. McNeil also waives all rights, whether asserted directly or by a representative, to

request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act, 5 U.S.C. § 552a.

13. McNeil is satisfied with the legal representation provided by its lawyers; McNeil and its lawyers have fully discussed this guilty plea agreement; and McNeil is agreeing to plead guilty because McNeil admits that it is guilty of the misdemeanor described in paragraph 1.

14. McNeil will acknowledge acceptance of this guilty plea agreement by the signature of its counsel and of an authorized corporate officer. McNeil shall provide to the government for attachment as Exhibit C to this plea agreement a notarized resolution by the McNeil Management Board authorizing the corporation to enter a plea of guilty, and authorizing a corporate officer to execute this agreement.

15. If acceptable to the Court, the parties agree to waive the presentence investigation and report pursuant to Rule 32(c)(1) of the Federal Rules of Criminal Procedure, and ask that McNeil be sentenced at the time the guilty plea is entered.

16. It is agreed that the parties' guilty plea agreement contains no additional promises, agreements or understandings other than those set forth in this written guilty plea agreement, and that no additional promises, agreements or understandings will be entered into unless in writing and signed by all parties.

SIGNATURES FOR THE UNITED STATES

BENJAMIN C. MIZER
Acting Assistant Attorney General
Civil Division
United States Department of Justice

LOUIS D. LAPPEN
First Assistant United States Attorney
United States Attorney's Office
For the Eastern District of Pennsylvania

MICHAEL S. BLUME
Director
Consumer Protection Branch
United States Department of Justice

MARY E. CRAWLEY
Chief, Government, Environment
and Health Care Fraud
Assistant United States Attorney

JEFFREY I. STEGER
Assistant Director
Consumer Protection Branch
United States Department of Justice

MARY BETH LEAHY
Assistant United States Attorney

DATE: 3/6/15

SIGNATURE FOR MCNEIL-PPC, INC.

DATE: 11/4/14

SHANE FREEDMAN, ESQ.
Secretary, McNEIL-PPC, Inc.

SIGNATURE OF MCNEIL'S ATTORNEY

DATE: 11/4/14

THOMAS M. GALLAGHER
Pepper Hamilton LLP
Counsel for Defendant

DATE: 11/4/14

MICHAEL A. SCHWARTZ
Pepper Hamilton LLP
Counsel for Defendant

DATE: 11/4/14

ETHAN M. POSNER
Covington & Burling LLP
Counsel for Defendant

DATE: 11/4/14

CHRISTOPHER M. DENIG
Covington & Burling, LLP
Counsel for Defendant

Exhibit A

ACKNOWLEDGMENT OF RIGHTS

Original signed document will be provided to the Court at the time of plea and sentencing.

EXHIBIT B

Exhibit B

U.S. Department of Justice

Criminal Division

Assistant Attorney General *Washington, D.C. 20530*

MAR 06 2015

The Honorable Louis D. Lappen
Acting United States Attorney
Eastern District of Pennsylvania
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106

Michael S. Blume
Director, Consumer Protection Branch
Civil Division
U.S. Department of Justice
450 Fifth Street, N.W.
Washington, D.C. 20001

Attention: Mary Crawley
Assistant United States Attorney

Jeffrey Steger
Assistant Director, Consumer Protection Branch

Re: Global Plea Agreement: McNeil-PPC, Inc.

Dear Mr. Lappen and Mr. Blume:

This letter is in response to your request for authorization to enter into a global plea agreement with McNeil-PPC, Inc. I hereby approve the terms of the plea agreement, including the provisions in paragraph 7, through which the United States, with the exception of the Criminal Division's Fraud Section, agrees not to initiate further criminal proceedings against McNeil-PPC, Inc., its present and former parents, affiliates, division and subsidiaries; and their predecessors, successors and assigns, for the conduct described in paragraph 7. You are authorized to make this approval a matter of record in this proceeding.

Sincerely,

Leslie R. Caldwell
Assistant Attorney General

Paul M. O'B

PAUL M O'BRIEN
DEPUTY ASSISTANT ATTORNEY GENERAL
CRIMINAL DIVISION

EXHIBIT C

Exhibit C

McNEIL-PPC, Inc.

McNeil Consumer Healthcare Division

The undersigned, being all of the duly appointed Members of the Management Board of the McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. ("MCH"), pursuant to Article III, Section 7 of the By-Laws, do hereby authorize and consent to the following action:

RESOLVED: that MCH recommends that McNeil-PPC, Inc. enter into a proposed federal resolution regarding the delivery of certain over-the-counter ("OTC") drugs, including entering into:

1. A plea agreement with the United States Attorney's Office for the Eastern District of Pennsylvania and the United States Department of Justice to plead guilty to a single misdemeanor count of violation of the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a), 333(a)(1) and 351(a)(2)(B), substantially in the form attached hereto;and
2. All other documents necessary to effectuate the settlement, and it is further;

RESOLVED: that MCH recommends that McNeil PPC, Inc., having been counseled on its legal rights and the factual basis for the plea as set forth in Federal Rule of Criminal Procedure 11(b), authorize legal representatives to enter into and execute a plea agreement substantially in the form attached hereto, and it is further;

RESOLVED: that any and all agreements executed on behalf of MCH or McNeil PPC, Inc. in connection with the transactions contemplated, and all further actions necessary to complete and effectuate those transactions, including the personal appearance in court to enter a plea of guilty on behalf of McNeil PPC, Inc. by a Director or authorized individual, including Joseph Braunreuther, Esq., as counsel representing the Company, hereby are ratified and approved.

Kirk M Barton

Shane H Freedman, Esq.

Denice Torres

Effective Date: November 4, 2014

CERTIFICATE OF SERVICE

IT IS HEREBY CERTIFIED that this document has been has been served by me on this date, by electronic case filing notification, upon:

Thomas M. Gallagher
Pepper Hamilton LLP
3000 Two Logan Square
18th and Arch Streets
Philadelphia, PA 19103
Gallagher@pepperlaw.com

/s M. Beth Leahy
MARY BETH LEAHY
Assistant United States Attorney

Date: March 10, 2015