

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services (“OIG-HHS”) (collectively the “United States”), Cephalon, Inc. (“Cephalon”), and Ronald J. Streck (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Cephalon is a company incorporated under the laws of Delaware with its headquarters in Frazer, Pennsylvania. At all relevant times, Cephalon manufactured and sold pharmaceutical products in the United States. In 2011, Teva Pharmaceuticals Industries Ltd. acquired Cephalon, and Cephalon became a wholly-owned subsidiary of Teva Pharmaceuticals.

B. On October 28, 2008, Relator filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States, State of California, State of Connecticut, State of Delaware, State of Florida, State of Georgia, State of Hawaii, State of Illinois, State of Indiana, State of Louisiana, The Commonwealth of Massachusetts, State of Michigan, State of Montana, State of Nevada, State of New Hampshire, State of New Jersey, State of New Mexico, State of New York, State of North Carolina, State of Oklahoma, State of Rhode Island, State of Tennessee, State of Texas, The Commonwealth of Virginia, State of Wisconsin, The District of Columbia, ex rel. Ronald J. Streck v. Allergan et al.*, 08-CV-5135, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) and the false claims statutes of

the plaintiff states (the “Civil Action”). Relator filed amended complaints in the Civil Action (which term, as used herein, includes the original and amended complaints) on or about January 12, 2009, May 20, 2010, April 25, 2011, and September 29, 2011.

Cephalon was named as a defendant in Relator’s original and amended complaints.

C. At all relevant times, Cephalon participated in the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5.

D. The United States contends that Cephalon made or caused to be made statements material to the payment of rebates pursuant to the Medicaid Drug Rebate Program and statements material to payments made by the United States to the states for the Medicaid Program.

E. The United States contends that it has certain civil claims against Cephalon for engaging in the following conduct during the period from January 1, 2007 through March 31, 2012 (hereafter referred to as the “Covered Conduct”):

1. Pursuant to the Medicaid Drug Rebate Program, Cephalon was required to report the Average Manufacturer Price (“AMP”) for each of its covered outpatient drugs to the Centers for Medicare and Medicaid Services (“CMS”) on a monthly and quarterly basis, and to pay quarterly rebates to state Medicaid programs that were based, in part, on the quarterly AMPs reported by Cephalon. Prior to enactment of the Affordable Care Act (“ACA”), the AMP for a drug generally was based on the average unit price paid to the manufacturer for the drug by wholesalers for drugs distributed to the retail pharmacy class of trade, including cash discounts and other price concessions that reduced the actual price paid for the drug. The ACA revised the

definition of AMP, in part, by replacing the term “retail pharmacy class of trade” with “retail community pharmacies” and including manufacturer direct sales to pharmacies. Both before and after enactment of the ACA, bona fide service fees are excluded from manufacturers’ AMP calculations.

2. Cephalon entered into distribution services agreements with wholesalers (“Distribution Services Agreements”) to facilitate the distribution and sale of the pharmaceuticals listed on Attachment A hereto (“the Covered Drugs”). Pursuant to the Distribution Services Agreements, the wholesalers performed various specified services, and Cephalon compensated the wholesalers for performing those services by providing the wholesalers quarterly credits calculated as a percentage of the quarterly sales of the Covered Drugs, subject to certain performance penalties based on criteria set forth in the agreements.

3. The United States contends that Cephalon improperly treated compensation provided to the wholesalers pursuant to the Distribution Services Agreements as price reductions, rather than as bona fide service fees, in calculating and reporting quarterly AMPs to CMS for the Covered Drugs. As a result of Cephalon’s reporting such improperly reduced AMPs, the United States contends that Cephalon underpaid quarterly rebates owed to the states for the Covered Drugs under the Medicaid Drug Rebate Program, and caused the United States to be overcharged for its payments to the states for the Medicaid Program.

F. Cephalon will be entering into separate settlement agreements, described in paragraph 1.b below (hereinafter referred to as the “Medicaid State Settlement Agreements”) with certain states and the District of Columbia in settlement of the

Covered Conduct. States with which Cephalon executes a Medicaid State Settlement Agreement in the form to which Cephalon and the National Association of Medicaid Fraud Control Units (“NAMFCU”) have agreed, or in a form otherwise agreed to by Cephalon and an individual state, are referred to herein as “Medicaid Participating States.”

G. This Settlement Agreement is made in compromise of disputed claims. The Agreement is neither an admission of facts or liability by Cephalon nor a concession by the United States that its claims are not well founded. Neither this Agreement, its execution, nor the performance of any obligation under it, including any payment, nor the fact of the settlement, is intended to be an admission of liability or wrongdoing by Cephalon.

H. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator’s reasonable expenses, attorneys’ fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Cephalon shall pay to the United States and the Medicaid Participating States, collectively, the sum of \$7,500,000.00 (“Settlement Amount”) and interest on the Settlement Amount at a rate of 2.125% per annum from September 26, 2014. The Settlement Amount shall constitute a debt immediately due and owing to the United

States and the Medicaid Participating States. The debt shall be discharged by payments to the United States and Medicaid Participating States as follows:

a. Cephalon shall pay to the United States the sum of \$4,319,528.56 plus interest thereon at a rate of 2.125% per annum from September 26, 2014 to and including the Effective Date of this Agreement (the “Federal Settlement Amount”).

Cephalon shall pay the Federal Settlement Amount to the United States by electronic funds transfer pursuant to written instructions to be provided by the United States by the Effective Date of this Agreement. Cephalon shall make this electronic funds transfer no later than five business days after the Effective Date of this Agreement.

b. Cephalon shall pay to the Medicaid Participating States the sum of \$3,180,471.44 plus interest thereon at a rate of 2.125% per annum from September 26, 2014 (the “State Settlement Amount”). The State Settlement Amount shall be paid by electronic funds transfer in accordance with written instructions to be provided by the NAMFCU negotiating team pursuant to the terms and conditions agreed upon by Cephalon and the NAMFCU negotiating team and as set forth in the Medicaid State Settlement Agreements that Cephalon will enter into with the Medicaid Participating States.

2. Cephalon shall pay to Relator the sum of \$500,000 for expenses, attorneys’ fees and costs (“Relator Expenses”) pursuant to an agreement previously reached between Cephalon and Relator, in accordance with written instructions to be provided by Relator’s counsel, in full and complete satisfaction of Relator’s statutory claim for reasonable attorneys’ fees, expenses and costs resulting from the Civil Action

pursuant to 31 U.S.C. § 3730(d). Cephalon shall make this payment no later than five business days after the Effective Date of this Agreement.

3. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon Cephalon's full payment of the Settlement Amount, the United States releases Cephalon, together with its current and former parents, subsidiaries, divisions, other affiliates (defined as an entity that controls, or is controlled by, Cephalon through common ownership), predecessors, successors, transferees, heirs and assigns, and their current and former directors, officers, partners, shareholders, representatives, agents, and employees (the "Cephalon Releasees"), from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8 (including any such claim for the Covered Conduct under the rebate agreement Cephalon executed pursuant to the statute or based on an administrative restatement of AMP pursuant to the statute); or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Subject to the exceptions in Paragraph 6 below, and conditioned upon Cephalon's full payment of the Settlement Amount and Relator Expenses, Relator for himself and for his heirs, successors, attorneys, agents, and assigns, releases the Cephalon Releasees from any civil monetary claim Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 and from all liability, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal

or state statute or regulation, or in common law, that Relator, his heirs, successors, attorneys, agents and assigns otherwise has or would have standing to bring as of the date of this Agreement, including any liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil Action. Other than for the Covered Conduct, this release does not apply to claims, if any, filed against Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals, USA, Inc., or Barr Laboratories, Inc., on or before May 15, 2015.

5. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Cephalon and/or its officers, directors, and employees from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion).

6. Notwithstanding the releases given in paragraphs 3 and 4 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;

- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due; or
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). In connection with this Agreement and this Civil Action, Relator and his heirs, successors, attorneys, agents, and assigns agree that neither this Agreement, any motion to intervene or intervention by the United States in the Civil Action in order to dismiss any portion of the Civil Action, nor any dismissal of any portion of the Civil Action, shall waive or otherwise affect the ability of the United States to contend that provisions in the False Claims Act, including 31 U.S.C. §§ 3730(d)(3) and 3730(e), bar Relator from sharing in the proceeds of this Agreement. The United States agrees that neither this Agreement, nor any dismissal of claims asserted against Cephalon in the Civil Action pursuant to this Agreement, shall waive or otherwise affect the ability of Relator to oppose intervention by the United States in the Civil Action, or to contend, should intervention occur, that Relator is entitled to a share of between 15% and 30% of the Federal Settlement Amount.

Moreover, the United States and Relator and his heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relator should receive of any proceeds of this Settlement Agreement, and that no agreements concerning Relator's share have been reached to date.

8. Conditioned upon Cephalon's full payment of the Relator Expenses pursuant to paragraph 2 of this Agreement, Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases Cephalon, and its officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d), for expenses or attorneys' fees and costs.

9. Cephalon waives and shall not assert any defenses Cephalon may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

10. Cephalon fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Cephalon has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers,

agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

11. Cephalon fully and finally releases Relator and his heirs, successors, attorneys, agents, and assigns, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Cephalon has, up to the date on which it executes this Agreement, that it has asserted, could have asserted, or may assert in the future against Relator and his heirs, successors, attorneys, agents, and assigns, related to the filing of the Civil Action and Relator's investigation and prosecution thereof.

12. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any federal or state payer related to the Covered Conduct; and Cephalon agrees not to resubmit to any federal or state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

13. Cephalon agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Cephalon, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Cephalon's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Cephalon makes to the United States or any State pursuant to this Agreement or the Medicaid State Settlement Agreements, and any payments that Cephalon may make to Relator, including costs and attorney's fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as "Unallowable Costs").

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Cephalon, and Cephalon shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Cephalon or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Cephalon further agrees that within 90 days of the Effective Date of this

Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Cephalon or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Cephalon agrees that the United States, at a minimum, shall be entitled to recoup from Cephalon any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Cephalon or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Cephalon or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Cephalon's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

14. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 15 (waiver for beneficiaries paragraph), below.

15. Cephalon agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

16. Upon receipt of the payment described in Paragraph 1.a, above, the United States shall promptly file in the Civil Action a motion to intervene in the Civil Action to effectuate this Settlement Agreement, request dismissal with prejudice of all claims asserted against Cephalon on behalf of the United States in the Civil Action for the Covered Conduct released in this Settlement Agreement, request dismissal of all claims asserted against Cephalon on behalf of the United States in the Civil Action for other than the Covered Conduct with prejudice to Relator but without prejudice to the United States or the States, and request that the Court retain jurisdiction over any unresolved matters concerning Relator's claim for a share of the proceeds of this Settlement Agreement pursuant to 31 U.S.C. § 3730(d). Relator reserves all rights to oppose intervention by the United States in the Civil Action, but Relator agrees to join the United States's request for dismissal of all claims asserted against Cephalon on behalf of the United States in the Civil Action, provided the Court agrees to retain jurisdiction over any unresolved matters concerning Relator's claim for a share of the proceeds of this Settlement Agreement pursuant to 31 U.S.C. § 3730(d).

17. Except as provided for in paragraph 2, above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

18. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Eastern District of Pennsylvania. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

20. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

21. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on Cephalon's successors, transferees, heirs, and assigns.

24. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

25. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

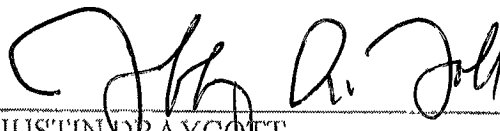
26. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement"). Facsimiles of signatures and/or electronic signatures in portable document format (.pdf) shall constitute acceptable, binding signatures for purposes of this Agreement.

[Remainder of page intentionally left blank; signature pages to follow.]

THE UNITED STATES OF AMERICA

DATED: 6/16/15

BY:



JUSTIN DRAYCOTT

JEFFREY A. TOLL

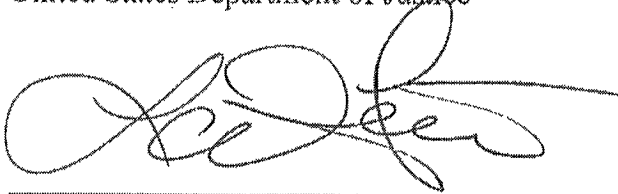
Trial Attorneys

Commercial Litigation Branch

Civil Division

United States Department of Justice

DATED: 6/11/15



LOUIS D. LAPPEN

First Assistant United States Attorney

Eastern District of Pennsylvania

DATED: 6/11/15



MARGARET L. HUTCHINSON

Chief, Civil Division

Assistant United States Attorney

Eastern District of Pennsylvania

DATED: 6/11/15



ERIC D. GILL

Assistant United States Attorney

Eastern District of Pennsylvania

DATED: _____

BY:



ROBERT K. DECONTI

Assistant Inspector General for Legal Affairs

Office of Counsel to the Inspector General

Office of Inspector General

United States Department of

Health and Human Services

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

JUSTIN DRAYCOTT
JEFFREY A. TOLL
Trial Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

LOUIS D. LAPPEN
First Assistant United States Attorney
Eastern District of Pennsylvania

DATED: _____

MARGARET L. HUTCHINSON
Chief, Civil Division
Assistant United States Attorney
Eastern District of Pennsylvania

DATED: _____


ERIC D. GILL
Assistant United States Attorney
Eastern District of Pennsylvania

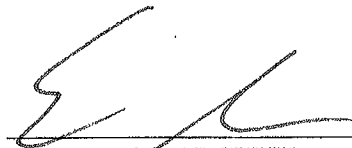
DATED: 6/15/15

BY: _____

Robert K. DeConti
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of
Health and Human Services

CEPHALON, INC.

DATED: 6/10/15 BY: 
LARRY DOWNEY
President, North America Special Medicines
Teva Pharmaceutical Industries Ltd.

DATED: 6/10/15 BY: 
ERIC W. SITARCHUK
REBECCA J. HILLYER
Morgan, Lewis & Bockius LLP
Counsel for Cephalon, Inc.

RONALD J. STRECK – RELATOR

DATED: 6/10/2015

BY: Ronald J. Streck
RONALD J. STRECK
Relator

DATED: 6/10/15

BY: Dan Miller
DANIEL R. MILLER
TODD S. COLLINS
Berger & Montague

and

DATED: 6/10/15

BY: Talyana Bromberg
TALYANA BROMBERG
Faruqi & Faruqi

Counsel for Ronald J. Streck

ATTACHMENT A COVERED DRUGS

NDC	DRUG NAME
63459-0100-01	Provigil 100mg
63459-0101-01	Provigil 100 mg
63459-0101-30	Provigil 100 mg
63459-0200-01	Provigil 200 mg
63459-0201-01	Provigil 200 mg
63459-0201-30	Provigil 200 mg
63459-0205-30	Nuvigil 50mg
63459-0205-60	Nuvigil 50mg
63459-0215-30	Nuvigil 150mg
63459-0215-60	Nuvigil 150mg
63459-0225-30	Nuvigil 250mg
63459-0225-60	Nuvigil 250mg
63459-0300-42	Vivitrol 380mg
63459-0390-08	Treanda 25mg/5mL
63459-0391-20	Treanda 100mg/20mL
63459-0402-01	Gabitril 2mg
63459-0402-30	Gabitril 2mg
63459-0404-01	Gabitril 4mg
63459-0404-30	Gabitril 4mg
63459-0412-01	Gabitril 12mg
63459-0412-30	Gabitril 12mg
63459-0416-01	Gabitril 16mg
63459-0416-30	Gabitril 16mg
63459-0502-30	Actiq 200 mcg
63459-0504-30	Actiq 400 mcg
63459-0506-30	Actiq 600 mcg
63459-0508-30	Actiq 800 mcg
63459-0512-30	Actiq 1200 mcg
63459-0516-30	Actiq 1600 mcg
63459-0541-28	Fentora 100mcg
63459-0542-28	Fentora 200mcg
63459-0543-28	Fentora 300mcg
63459-0544-04	Fentora 400mcg
63459-0544-28	Fentora 400mcg
63459-0546-04	Fentora 600mcg
63459-0546-28	Fentora 600mcg
63459-0548-04	Fentora 800mcg
63459-0548-28	Fentora 800mcg
63459-0600-10	Trisenox 100 mg
63459-0700-60	Amrix 15 mg
63459-0701-60	Amrix 30mg