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# U.S. Department of Justice

United States Attorney
District of New Jersey

970 Broad Street, Suite 700 Newark, NJ 07102 973/645-2700

JM/SS/PL AGR 2008R00799

January 3, 2013

John N. Nassikas, Esq. Baruch Weiss, Esq. Laura Lester, Esq. Arnold & Porter LLP 555 Twelfth Street, NW Washington, DC 20004-1206

Re: Plea Agreement with Par Pharmaceutical Companies, Inc.

Dear Mr. Nassikas:

This letter sets forth the plea agreement between your client, Par Pharmaceutical Companies, Inc. ("Par") and the United States Attorney for the District of New Jersey ("this Office").

### Charge

Conditioned on the understandings specified below, this Office will accept a guilty plea from Par to a one-count Information, which charges Par with introducing or delivering a misbranded drug into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1). If Par enters a guilty plea and a judgment of conviction is entered that is consistent with terms of the agreed disposition included in this plea agreement under Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, and if Par otherwise fully complies with all of the terms of this agreement, this Office will not initiate any further criminal charges against Par or any of its subsidiaries, including Par Pharmaceutical, Inc., with respect to its sales, marketing and promotion of Megace® ES from July 2005 to the present. However, in the event that a guilty plea in this matter is not entered for any reason or the judgment of conviction entered as a result of this guilty plea does not remain in full force and effect, Par agrees that any dismissed charges and any other charges that were not time-barred by the applicable statute of limitations on the date the tolling agreements were executed by the parties may be commenced against Par, notwithstanding the expiration of the limitations period after the date of the tolling agreements and/or the date Par signs the agreement.



### Sentencing

The violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1) to which Par agrees to plead guilty carries a statutory maximum term of probation of 5 years, and a statutory maximum fine equal to the greatest of: (1) \$200,000; (2) twice the gross amount of any pecuniary gain that any persons derived from the offense; or (3) twice the gross amount of any pecuniary loss sustained by any victims of the offense. See 18 U.S.C. §§ 3561(c)(2), 3571(c)(5), 3571(d). Fines imposed by the sentencing judge may be subject to the payment of interest.

Further, in addition to imposing any other penalty on Par, the sentencing judge: (1) will order Par to pay an assessment of \$125 pursuant to 18 U.S.C. § 3013, which assessment must be paid by the date of sentencing; and (2) may order Par to pay restitution pursuant to 18 U.S.C. § 3563.

The parties agree that while the fine provisions of the United States Sentencing Guidelines ("U.S.S.G.") do not apply to organizational defendants for misdemeanor violations of the Federal Food, Drug, and Cosmetic Act, see U.S.S.G. § 8C2.1, the fine agreed upon by the parties is consistent with the U.S.S.G. and takes into account Par's conduct under 18 U.S.C. § 3553 and 3572, as follows:

- (1) The parties agree that the base fine is \$11,000,000, in that such amount was the reasonably estimated pecuniary gain to Par from the offense, see U.S.S.G. §§ 8C2.3, 8C2.4(a);
- (2) Pursuant to U.S.S.G. § 8C2.5, the culpability score is seven (7), which is determined as follows:
  - (i) base culpability score of five (5) pursuant to U.S.S.G. § 8C2.5(a);
  - (ii) add three (3) points pursuant to U.S.S.G. § 8C2.5(b)(3)(A) because the organization had 200 or more employees, and an individual within high-level personnel of the organization participated in, condoned, or was willfully ignorant of the offense; and
  - (iii) deduct one point for Par's acceptance of responsibility for its criminal conduct pursuant to U.S.S.G. § 8C2.5(g)(3).



- (3) Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of seven (7) is 1.4 to 2.8; and
- (4) Therefore, the advisory Guidelines Fine Range is \$15,400,000 to \$30,800,000.

This Office and Par agree that, pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), the appropriate disposition of the case is as follows, and will result in the imposition of a reasonable sentence that is sufficient, but not greater than necessary, taking into consideration all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572:

- (1) Par shall pay a criminal fine in the amount of \$18,000,000 within seven (7) days after sentencing;
- (2) Par shall pay a special assessment of \$125;
- (3) Par shall be subject to pay forfeiture in the amount of \$4,500,000, and such amount shall be paid prior to the time of the plea hearing;
- (4) The United States agrees that it will not seek a separate restitution order as to Par as part of the resolution of the charge in the Information. The United States and Par agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a restitution order outweighs the need to provide restitution to non-governmental victims, if any, in this case; and
- (5) The United States further agrees that it will not seek a term of probation in light of: (i) the remedial measures undertaken by Par to date; (ii) the enhanced corporate rehabilitative compliance measures and certifications agreed to by Par as attached hereto as Exhibit 1; and (iii) the Corporate Integrity Agreement entered into between Par and the Office of the Inspector General of the Department of Health and Human Services, attached hereto as Exhibit 2.

Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), this Office and Par agree that no other sentence or



fine is appropriate, beside those set forth above. If the Court accepts this plea agreement, Par must be sentenced accordingly. If the Court rejects any aspect of this plea agreement or fails to impose a sentence consistent herewith, this agreement shall be null and void at the option of either the United States or Par, except that Par expressly waives, and agrees that it will not interpose, any defense to any charges brought against Par which Par might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act. If Par fails to pay any amounts within the time frames specified in this plea agreement, this agreement shall be null and void at the sole option of the United States. See 18 U.S.C. § 3614.

### Other Litigations

Par agrees that it will, before the time of entry of the guilty plea in this matter, at the Government's request, file a motion to strike those portions of pages 10 and 11 of Par's March 23, 2012 submission in Par Pharmaceutical, Inc. v. United States of America, et al., 11-CV-1820 (RC) (JMF), identifying specific conversations with government attorneys. In withdrawing these portions, Par will state that it does not concede that the discussions included are protected or privileged, or that their inclusion in Par's briefs constitutes any violation of a rule, regulation, or statute (including Fed. R. Evid. 408 and 410).

Par also agrees that it will, before the time of entry of the guilty plea in this matter, execute and provide to the Government executed copies of a joint stipulation of dismissal with prejudice for each of the actions entitled Par Pharmaceutical, Inc. v. United States of America, et al., 11-CV-1820 (RC) (JMF), and In re Grand Jury Matter, 11-2679 (3d Cir.). Par further agrees that it will file these stipulations of dismissal immediately upon the completion of sentencing in this matter. If Par fails to file those stipulations of dismissal immediately upon the completion of sentencing, the Government is hereby authorized to file those joint stipulations of dismissal on Par's behalf.

### Rights of the Parties Regarding Sentencing

Except as otherwise provided in this agreement, all parties to this agreement reserve their rights to correct any misstatements relating to the sentencing proceedings, and to provide the sentencing judge and the United States Probation Office all law and information relevant to sentencing, favorable or otherwise. In addition, the parties may inform the sentencing



judge and the United States Probation Office of: (1) this agreement; and (2) the full nature and extent of Par's activities and relevant conduct with respect to this case.

### Waiver of Appeal and Post-Sentencing Rights

Par knowingly and voluntarily waives the right to file any appeal, any collateral attack, or any other writ or motion, including but not limited to an appeal under 18 U.S.C. § 3742 or a motion under 28 U.S.C. § 2255, which challenges the conviction or sentence imposed by the Court if the plea is accepted and the sentence is imposed in accordance with the terms of this agreement.

This Office will not file any appeal, motion or writ which challenges the conviction or sentence imposed by the Court if that sentence is imposed in accordance with the terms of this agreement. Furthermore, if the Court accepts the terms of this plea agreement, both parties waive the right to file an appeal, collateral attack, writ, or motion claiming that the Court erred in doing so.

Both parties reserve the right to oppose or move to dismiss any appeal, collateral attack, writ, or motion barred by the preceding paragraphs.

# <u>Forfeiture</u>

Par agrees that as part of its acceptance of responsibility, Par will forfeit to the United States assets subject to forfeiture pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c). Par admits that the value of the quantities of Megace® ES that were misbranded and distributed in violation of 21 U.S.C. § 331 totaled approximately \$4,500,000 in United States currency.

Par acknowledges and agrees that the quantities of Megace® ES which were misbranded and distributed in violation of 21 U.S.C. § 331 cannot be located upon the exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, Par agrees that the United States is entitled to forfeit as "substitute assets" any other assets of Par up to the value of the now-missing directly forfeitable assets.

Par agrees that, before the time it enters a plea of guilty pursuant to this agreement, it shall remit the amount of



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