

## U.S. Department of Justice

## United States Attorney District of Massachusetts

Main Reception: (617) 748-3100

United States Courthouse, Suite 9200 1 Courthouse Way Boston, Massachusetts 02210

September 21, 2011

By e-mail and fax 202-778-5281

Geoffrey Hobart, Esq. Covington & Burling 1210 Pennsylvania Avenue, NW Washington, DC 20004-3401

Re: GlaxoSmithKline LLC - Avandia CV: Tolling Agreement on Statute of Limitations

Dear Mr. Hobart:

This letter confirms and sets forth an agreement between the Office of the United States Attorney for the District of Massachusetts and your client, GlasoSmithKline LLC, and all successors and assigns (hereinafter "GSK"). The terms of the agreement are as follows:

- 1. As you are aware, this Office is presently conducting a joint criminal and civil investigation of your client, GSK, and its officers, employees and agents. That conduct includes, without limitation, allegations that GSK and certain of its officers, employees and agents, may have violated various federal criminal statutes, including but not limited to 18 U.S.C. §371 (conspiracy to defraud the United States), 18 U.S.C. § 1001 (making false or fraudulent statements), 21 U.S.C. § 301, et seq. (Food Drug & Cosmetic Act), health care fraud offenses (e.g. 18 U.S.C. §§ 669, 1347, and 1035), certain civil statutes including but not limited to 31 U.S.C. § 3729 (civil False Claims Act); and certain administrative statutes such as 42 U.S.C. § 1320a-7 (exclusion) and 42 U.S.C. § 1320a-7a (civil monetary penalties) in connection with (a) suppression of negative information about the cardiovascular risk of Avandia, (b) statements that minimized the cardiovascular risks of Avandia to physicians, the FDA, and others, and/or (c) efforts to prevent full and fair information about the cardiovascular risks of Avandia reaching the public, physicians, the FDA, and/or others.
- 2. In the course of our discussions, this Office has expressed its intention to afford you and your client the fullest opportunity to provide information to this Office which you deem relevant to matters relating to that investigation. In response, you have advised us that you intend to provide certain information to this Office, and that you wish such information be

considered prior to a prosecution decision concerning potential criminal charges resulting from that investigation. You have advised this Office that you and members of your firm will require a further time period to prepare any materials and gather information for presentation to this Office, and to consider and evaluate further information as may be provided by this Office. As a result, this Office and your client have agreed, as more fully set forth below, to toll the applicable statutes of limitations for the offenses described in paragraph one for the time period May 1, 2010 through October 1, 2012 for that conduct described in paragraph one.

- This Office and your client, GSK, hereby agree that your client will not at any time interpose a statute of limitations defense or any constitutional claim based upon pre-indictment delay to any indictment or count thereof, or to any civil complaint or count thereof, or to any administrative action, which charges or alleges that your client committed any federal offense or violation related to the conduct described in paragraph one, that includes the time period May 1, 2010 to October 1, 2012 in the calculation of the limitations period. Nothing herein shall affect, or be construed as any waiver of, any applicable statute of limitations defenses that GSK may have with respect to the time period prior to and including May 1, 2010, and your client expressly reserves its right to raise any such defense, any provisions of this agreement notwithstanding, except to the extent that your client has waived certain statute of limitation defenses in any waiver agreement(s) with other United States Attorney's Offices or the Department of Justice, which agreement(s) remain in effect.
- 4. Your client, GSK, enters into this agreement knowingly and voluntarily. GSK acknowledges that the statute of limitations and United States Constitution regarding prejudicial pre-indictment delay confers benefits on it, and it is not required to waive those benefits, and that GSK is doing so after consulting with you because GSK believes it is in its best interest to do so. GSK also acknowledges its understanding that it may be charged with the foregoing criminal offenses and civil and administrative violations and/or any other offenses or violations at any time prior to and including October 1, 2012. GSK further acknowledges its understanding that it may be charged with any offenses or violations not specifically described above, at any time during the relevant statute of limitations period.
- 5. This agreement relates only to the allegations described in Paragraph one above and any charges or claims based on those allegations. This writing contains the entire agreement between this Office and your client and can be modified or supplemented only by means of a writing signed by this Office and your client.

If your client is willing to enter into this agreement on the terms set forth above, GSK should indicate the same by signing on the spaces provided below and by initialing each page of this agreement. Please return an executed original to the undersigned by October 1, 2011.

Very truly yours,

CARMEN M. ORTIZ United States Attorney

By:

/s/ Susan Winkler Susan G. Winkler Assistant U.S. Attorney

Geoffrey Hobart Covington & Burling

Attorney for GSK

Dated: 9/27/11

Name: Elpidio Villoured
Position: SVP - Global Litigation
GlaxoSmithKline LLC