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 16 **UNITED STATES DISTRICT COURT**  
 17 **NORTHERN DISTRICT OF CALIFORNIA**  
 18 **SAN FRANCISCO DIVISION**

19 UNITED STATES <i>ex rel.</i> RICARDO FORGES, ) et al., )	No. C 08-4986 CRB
20 Plaintiffs, )	<b>REQUEST FOR ENLARGEMENT OF      TIME TO ELECT OR DECLINE TO      INTERVENE; [<del>PROPOSED</del>] ORDER</b>
21 v. )	
22 CV THERAPEUTICS, INC., ) Defendant. )	

24  
 25 The United States of America, through their undersigned counsel of record, hereby  
 26 request that the Court enlarge the extension by fifteen days, until December 15, 2010 the period  
 27 during which the United States may elect to intervene in the above-captioned False Claims Act  
 28 (FCA) *qui tam* action or to notify the Court that it declines to do so, and during which the

1 complaint and other filings shall remain under seal. This is the sixth and final request for an  
2 extension of the intervention and seal deadline. On June 21, 2010, the United States and Relator  
3 requested that the Court extend the intervention deadline until January 6, 2011. Also on June 21,  
4 2010, the Court granted the request but only extended the deadline to October 1, 2010. On  
5 September 17, 2010 the United States and Relator requested that the Court extend the deadline  
6 until December 1, 2010, and the Court granted the request.

7 1. This application is being filed *ex parte* pursuant to Civil L.R. 7-10 and the Federal FCA,  
8 31 U.S.C. §§ 3729-3733, and is not being served on Defendants because the matter currently  
9 remains under seal pursuant to the FCA and order of this Court. This filing is being served on  
10 the Relator, Ricardo Forges.

11 2. This action was filed on October 30, 2008 under the *qui tam* provisions of the Federal and  
12 various State FCAs. Among other things, these provisions authorize private parties (known as  
13 relators) to file lawsuits alleging FCA violations on behalf of the United States and the States,  
14 respectively. 31 U.S.C. § 3730(b). Relator alleges violations of twenty separate State FCAs.  
15 See Complaint at ¶¶ 97-262.

16 3. In this action Forges, as Relator, alleges, *inter alia*, that Defendant CV Therapeutics, Inc.  
17 violated the Federal and State FCAs by marketing the drug Ranexa for uses not approved by the  
18 United States Food and Drug Administration as part of the drug's labeling (known as "off-label  
19 marketing"). Relator also alleges that Defendant utilized various types of kickbacks to  
20 physicians and other health care providers to induce them to prescribe Ranexa. Relator alleges  
21 that the federal health care programs paid claims for Ranexa that were false because they were  
22 the result of off-label marketing and/or induced by kickbacks.

23 4. On or about April 15, 2009, Defendant CV Therapeutics, Inc. was acquired by Gilead  
24 Sciences, Inc ("Gilead"). On August 21, 2009, Relator filed a First Amended Complaint which,  
25 *inter alia*, included allegations regarding Gilead's acquisition of CV Therapeutics, and added  
26 Gilead as a party defendant.

27 5. Under 31 U.S.C. § 3730(b)(2), a *qui tam* complaint shall remain under seal for 60 days  
28 and shall not be served on the defendant until the court so orders. Before a *qui tam* complaint is

1 unsealed and served upon the defendant, the United States must elect whether it will intervene in  
2 and assume prosecution of the action or, instead, elect to decline intervention and permit the  
3 relator to carry on with the action on behalf of the government. 31 U.S.C. § 3730(b)(4). The  
4 States have similar obligations under the State FCAs. See, e.g., Cal. Gov't. Code §  
5 12652(c)(8)(B). The *qui tam* provisions of the Federal FCA expressly contemplate that motions  
6 for extensions of the 60-day period will be permitted upon a showing of "good cause." 31 U.S.C.  
7 §§ 3730(b)(2) & (3).

8 6. In the present case, the Court has granted five extensions of the seal period, until  
9 December 1, 2010. In its order dated June 23, 2009, the Court also ordered that the seal be  
10 partially lifted to allow the United States, at its option, to disclose the Relator's complaint and  
11 evidence to Defendant.

12 7. The United States has completed its investigation and is close to making an informed  
13 decision on intervention. However, attorneys for the government require a small amount of  
14 additional time to obtain the internal approvals needed before the government's intervention  
15 decision can be filed with the Court. The United States expects that it will be in a position to  
16 make that filing on or before December 15, 2010. Accordingly, the government seeks a fifteen-  
17 day extension of the seal and intervention deadlines in the present case, until December 15, 2010.

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1 8. Based on the foregoing, the Government respectfully requests a 15-day extension of the  
2 seal and intervention deadlines in the present case until December 1, 2010. During the extension  
3 period, if granted, the government will obtain the internal approvals needed before the  
4 government's intervention decision can be filed with the Court. With the exception of the partial  
5 lifting of the seal allowing the Government to discuss the Relator's allegations with Defendant,  
6 the United States asks that the case remain under seal for all other purposes.

7 Respectfully submitted,

8 TONY WEST  
Assistant Attorney General

9 MELINDA HAAG  
United States Attorney

10  
11  
12 DATED: 11/19, 2010

By:   
13 STEVEN J. SALTIEL  
Assistant United States Attorney  
Attorneys for United States

14  
15  
16  
17 **[PROPOSED] ORDER**

18 For good cause shown, IT IS HEREBY ORDERED that:

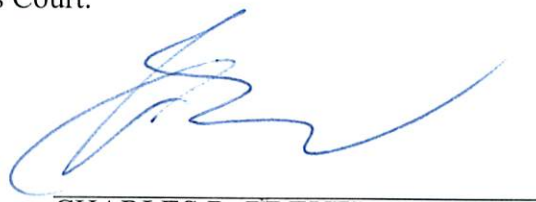
19 1. The United States shall have up to and including December 15, 2010, to inform this  
20 Court of its decision whether to intervene in this matter.

21 2. The seal in this case shall remain partially lifted to allow the United States, at its  
22 option, to reveal the existence of this *qui tam* action, and disclose the Relator's complaint and  
23 evidence to Defendant; and

24 3. Except as expressly stated herein, all pleadings and other documents filed in this action  
25 shall remain under seal until further order of this Court.

26 IT IS SO ORDERED.

27  
28 Dated: Nov. 22, 2010

  
CHARLES R. BREYER  
United States District Judge