

FILE COPY

Victor Raczkowski, M.D.
Vice President, U.S. Regulatory Affairs
Solvay Pharmaceuticals, Inc.
901 Sawyer Road
Marietta, GA 30062

October 18, 2007

Re: Docket No. 2007P-0363/CPI

Dear Dr. Raczkowski:

I am writing regarding your citizen petition received on September 28, 2007, and filed on September 28, 2007, requesting that the Food and Drug Administration (FDA or Agency) "(1) prevent false and misleading labeling and (2) ensure safe and efficacious use of dronabinol, in each case, by requiring abbreviated new drug applications (ANDAs) for generic versions of Marinol to contain the indication and important safety information for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional treatments *and* the indication and important safety information for the treatment of appetite loss associated with weight loss in patients with AIDS" (Petition at 1). It has come to the attention of the Division of Dockets Management that your citizen petition cannot be reviewed because it does not contain the certification required by section 914 of the Food and Drug Administration Amendments Act of 2007, which was enacted on September 27, 2007 (Public Law 110-85) (FDAAA).

Section 914 of FDAAA amends section 505¹ of the Federal Food, Drug, and Cosmetic Act (the Act) by adding a new subsection (q), which took effect on the date of enactment. The new subsection 505(q) governs citizen petitions and petitions for stay of Agency action that request that FDA take any form of action relating to a pending application submitted under sections 505(b)(2) or 505(j)² of the Act (copy of section 914 of FDAAA enclosed). Because your petition requests that FDA take an action relating to any pending ANDA for a generic version of Marinol, which would be submitted under 505(j), your petition is subject to the requirements of subsection 505(q). In particular, section 505(q)(1)(H)³ of the Act provides that FDA shall not consider a petition for review unless it contains the following certification:

I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that

¹ 21 U.S.C. 355.

² 21 U.S.C. 355(b)(2) or (j).

³ 21 U.S.C. 355(q)(1)(H).

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any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____[in the blank space, provide the date on which such information first became known to such party]. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ [in the blank space, provide the names of such persons or organizations]. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

Because your petition did not contain this certification, we may not consider your petition for review. If you wish to have the Agency review your petition, you must submit a petition that contains the certification required by FDAAA and described above.

Sincerely,

Carolyn C. Kachovec
Director
Division of Dockets Management
Office of Management Programs
Office of Management

Enclosure