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The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

We are writing on behalf of Sepracor Inc. ("Sepracor"), whom we represent, to request that the FDA provide an expeditious substantive response to the company's outstanding Citizen's Petition. More specifically, on December 30, 2005, Sepracor submitted a Citizen's Petition (2006P-0001) requesting FDA to: (1) confirm that the approval date for Lunesta® (eszopiclone) tablets ("Lunesta") became effective on April 4, 2005; (2) confirm that the five-year exclusivity for Lunesta commenced on the date of effective approval, April 4, 2005; and (3) confirm that the patent-term extension for Lunesta should be calculated based on the date of effective approval, April 4, 2005. We are writing today to urge FDA to issue a substantive response to Sepracor's Citizen's Petition as soon as possible, but certainly no later than November 25, 2008.

On December 15, 2004, FDA issued a letter addressing Sepracor's NDA filing for Lunesta. The final effective approval of Lunesta, however, did not occur when FDA issued the December 15, 2004 letter. Rather, it occurred on April 4, 2005 when the Drug Enforcement Administration, pursuant to FDA's statutorily-mandated request, completed the rulemaking process by which Lunesta was classified as a Schedule IV controlled substance under the Controlled Substances Act. Sepracor's Citizen's Petition formally requested that the FDA explicitly confirm that fact for all interested parties. Despite the critical importance of clarifying the effective approval date for Lunesta – to Sepracor, FDA, and others – FDA has thus far failed to provide a substantive response to the Citizen's Petition.

In a July, 2008, communication between Sepracor's counsel and FDA's Office of the Chief Counsel, Sepracor was pleased to learn that a substantive response to Sepracor's Citizen's Petition was "imminent." Nevertheless, FDA has not yet issued its response. While Sepracor has been patient during this nearly three-year process, the timing of an FDA response to Sepracor's Citizen's Petition has become critical. See: 21 U.S.C. §§ 505(j)(2)(A)(vii)(IV) and

FDA-2006-P-0137 LET

505(j)(5)(F)(ii). Accordingly, we respectfully request that FDA issue a substantive response to Sepracor's Citizen's Petition as soon as possible, and at the latest by November 25, 2008.

Please contact me if you have any questions.

Sincerely,

David J. Farber
Counsel for Sepracor

DJF:kph