September 5, 2018

Change Request for OMB #0923-0041: National Amyotrophic Lateral Sclerosis (ALS) Registry

Justification/Brief Explanation for the Change Request

This is a nonmaterial/non-substantive change request for the National ALS Registry (OMB Control No. 0923-0041 (expiration date: November 30, 2019).

We are requesting to add a question to Survey 17 about the use of a newly FDA approved drug, Radicava, for the treatment of ALS. FDA announced its approval on May 5, 2017 at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm557102.htm. Radicava is only the 2nd drug approved by FDA for the treatment of ALS.

Below is the requested change to previously approved Question 4 in Survey 17. The overall number of respondents and requested burden hours remain the same.

As such, we would appreciate your expedited consideration of this request.

Attachment	CURRENT VERSION	NEW VERSION
Survey 17	**4. Have you taken the drug riluzole (Rilutek®)?** I have never taken riluzole I used to take riluzole but discontinued it I am currently taking riluzole Don't know	**4. The following questions are about ALS specific medications you may have taken:** **4a. Have you taken the drug riluzole (Rilutek®)?** I have never taken riluzole I used to take riluzole but discontinued it I am currently taking riluzole Don't know **4b. Have you taken the drug edaravone (Radicava®)?** I have never taken edaravone I used to take edaravone but discontinued it I am currently taking edaravone Don't know

SUPPLEMENTAL DOCUMENTS

A. Revised Survey 17 Question 4 (screenshot)
B. Revised Survey 17 Question 4 (Word)