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.

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| **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**

1. Revised Survey 17 Question 4 (screenshot)
2. Revised Survey 17 Question 4 (Word)