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Department of Health and Human Services
Division of Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Response to Kaiser Permanente Citizen Petition Docket No. FDA-2009-P-0602-0001

Submitted via the Federal e-Rulemaking Portal: *http://www.regulations.gov*

On December 22, 2009, Kaiser Permanente filed a Citizen Petition regarding the Risk Evaluation and Mitigation Strategies (REMS) programs required under the Food and Drug Administration Amendments Act (FDAAA). In the spirit of further improving the effectiveness of REMS programs and optimizing therapeutic benefit/risk for patients, Amylin Pharmaceuticals, Inc. (Amylin) would like to take the opportunity to provide input to the Agency relative to key messages communicated in the petition.

Specifically, the petition requested that the FDA revise its standards and procedures associated with REMS to comply fully with FDAAA. These included increasing FDA transparency in the process of developing REMS, making safety summary data collected by REMS activities publically available, and ensuring that health care professionals (HCPs) are included in regular review of REMS programs that include elements to assure safe use (ETASU) to ensure effectiveness of the REMS programs. Additionally, Kaiser Permanente requested that HCP certification programs associated with some ETASU not unfairly limit the ability to prescribe, dispense or administer drugs subject to REMS to patients that could benefit from such therapies due to use of a specified specialty pharmacy drug distribution/dispensing company which may not be universally available.

Amylin fully supports a more timely and transparent approach to the development of all REMS. Dialogue on the details of a REMS need to occur significantly earlier in the review process, preferably if possible at the end of phase 2 or pre-NDA meeting for some items and no later than the Day 74 letter following NDA submission unless new safety information emerges. Currently, the Office of Safety and Epidemiology (OSE) will not discuss a REMS program until the label negotiations are close to completion, thus delaying any effective dialogue between sponsor and FDA until the final stages of the review process. Due to late REMS discussions, review extensions are frequently required which further delays timely patient access to new therapies.

For REMS that require ETASU, Amylin supports the concept of including this topic in an Advisory Committee, where appropriate, in parallel with the BLA/NDA review. This forum would allow input from HCPs on recommendations regarding ETASU elements. REMS containing ETASU elements should be standardized where possible across products and consonant with existing care delivery system workflows to minimize undue delivery system resource demands.

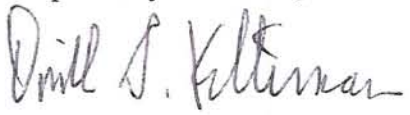
Amylin supports making public the protocols and data associated with REMS utilizing a standardized format and timing that would be used by all sponsors. Due to the complexities of some REMS, Amylin recommends that a respected impartial third-party professional medical association with the appropriate medical expertise act as a resource to assist in interpreting the data related to the focus of the REMS and advising on their relevance in clinical decision-making.

Amylin supports the use of REMS as long as the value of the mitigation strategies in minimizing identified risks is demonstrated. In particular, REMS with ETASU elements should undergo regular review to assess their effectiveness. HCPs and impartial third-party professional medical associations should be included in the evaluation process. In situations where value is not demonstrated, the ETASU elements need to be changed so that value can be demonstrated.

The content of a REMS, including certification requirements, should not restrict access to willing and qualified health care providers. It is in the interest of patients, HCPs, regulators, and sponsors that REMS requirements not constrain patient access to therapies that can provide incremental benefit where the benefit-risk balance is positive.

In summary, Amylin believes that earlier and more transparent dialogue between the sponsor and the FDA will lead to better REMS programs. For REMS that require ETASU, practicing HCPs and impartial third-party professional medical associations should have the opportunity to provide input in the original design as well as in periodic re-evaluation of the REMS to assist in better ensuring that REMS do not limit access to patients who could truly benefit from a therapy or unduly burden the health care delivery system. Amylin believes that protocols and study data generated from REMS activities should be available to the public utilizing a standardized format and timing that all sponsors should use. Where possible, we would recommend that respected impartial third-party professional medical associations of the appropriate specialty be utilized to assist in the interpretation of this data and advising on its relevance in clinical decision-making.

Respectfully submitted,



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