



November 20, 2014

Margaret A. Hamburg, MD, Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-N-0502

Dear Commissioner Hamburg:

As the national continuing education accreditors for the professions of medicine, pharmacy, and nursing, we share the FDA's aspiration to leverage the accredited continuing education (CE) system to deliver REMS to health care professionals, as described in your report *Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS)*.

We fully support and stand ready to facilitate the development and implementation of the process described in the report in "Project 2: Health Care Provider Education under REMS." In our roles as collaborating CE accreditors in the health professions, we are well-positioned to ensure that REMS CE activities are in compliance with our standards. We believe that it is feasible for accredited CE to address single products under REMS, provided the proper controls are in place to ensure independence.

We commend FDA for listening to stakeholders and for its commitment to evaluating and improving REMS. In order to support the goals and deliverables described in your report, we would welcome the opportunity to share the lessons learned from the implementation of the Extended-Release and Long-Acting Opioid Analgesics REMS.

We believe that accredited CE can play a significant role in addressing the patient safety issues identified in REMS. We appreciate that the FDA recognizes the value of accredited CE and is exploring how to leverage the accredited CE system to carry out these important public health initiatives. We look forward to our continued engagement.

Yours truly,

For the Accreditation Council for
Continuing Medical Education

Murray Kopelow, MD
President and Chief Executive
Officer

For the Accreditation Council for
Pharmacy Education

Peter H. Vlasses, PharmD
Executive Director

For the American Nurses Credentialing
Center

Kathy Chappell, PhD, RN
VP, Accreditation Program and
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