



Sunny Point State Park - Pittsburgh

PIC QUESTION OF THE WEEK: 7/20/09

Q: Please describe the REMS program recently initiated by the Food and Drug Administration.

A: The Food and Drug Administration Amendments Act (FDAAA) of 2007 included a provision that would require manufacturers to submit and subsequently implement a plan that would ensure rigid monitoring and surveillance of specific medications. The program, entitled Risk Evaluation and Mitigation Strategy (REMS), was to be applied to a select group of older medications as well as any newly approved products that met the following general criteria:

- health care providers who prescribe the drug have particular training or experience, or are specially certified;
- pharmacies, practitioners, or health care settings that dispense the drug are specially certified;
- the drug is dispensed to patients only in certain health care settings, such as hospitals;
- the drug is dispensed to patients with evidence or other documentation of safe use conditions, such as laboratory test results;
- each patient using the drug is subject to certain monitoring; or
- each patient using the drug is enrolled in a registry (see section 505-1(f)(3) of the Act).

The deadline for manufacturers to submit REMS proposals for drugs already meeting any of the above criteria was September 21, 2008 (see references below). Thereafter, a REMS had to be submitted for any *new* drug meeting these criteria as well as *previously marketed* products for which new information suggested increased patient risk(s). The critical objective of the program is to determine whether the benefits of a pharmaceutical product continue to clearly outweigh its risks. Individual REMS usually consist of some combination of Medication Guide and/or Patient Package Insert, surveillance, communication and assessment plans, and a timetable for implementation of the proposed strategy. Examples of *marketed* products for which a REMS had to subsequently be submitted and approved included romiplostim (Nplate), alvimopam (Entereg), and, most recently, propoxyphene. Dronaderone (Multaq), an antiarrhythmic similar to amiodarone, was recently marketed, but only after FDA approval of a specific REMS. As stated earlier, the primary purpose of the REMS program is to provide assurance of a positive benefit to risk ratio for pharmaceutical products.

References:

- Anticipating REMS. *Nat Rev Drug Discov* 2008;7:963.
- Food and Drug Administration. FDA identifies first steps in requirements for safety plans for certain drugs and biologics. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116872.htm> . Accessed July 7, 2009.
- Food and Drug Administration. Questions and answers on the federal register notice on drugs and biological products deemed to have risk evaluation and mitigation strategies. <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/ucm095439.htm> . Accessed July 7, 2009.

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The PIC Question of the Week is a publication of the Pharmaceutical Information Center, Mylan School of Pharmacy, Duquesne University, Pittsburgh, PA 15282 (412.396.4600).