Two unrelated events that occurred at the end of the lame duck Congress underscore the tasks that the Food and Drug Administration (FDA) will be facing in 2007—challenges that the agency had begun to attack, with little notice, in 2006.

On December 7, a day before the 109th Congress adjourned, the Senate finally approved Andrew von Eschenbach, MD, as Commissioner of the FDA. Dr. von Eschenbach, who had formerly headed the National Cancer Institute, had actually been nominated more than a year ago by President Bush. However, key senators held up a vote for various reasons. Senator Charles Grassley (R-Iowa), Chairman of the Finance Committee, had been the chief roadblock, claiming that the FDA was stonewalling his committee’s investigation of the antibiotic telithromycin (Ketek, Sanofi-Aventis).

On the same day that the Senate cleared Dr. von Eschenbach, Congress also passed a bill formally requiring adverse drug events (ADEs) reporting for over-the-counter (OTC) drugs. Up until then, reports were required only for OTC drugs that had once been sold on a prescription-only basis. That left out the vast majority of OTC drugs (sometimes called monograph drugs). When the FDA approves one of these drugs, it publishes a monograph that spells out the drug’s labeling requirements. Some marketers of monograph nonprescription drugs have submitted ADE reports voluntarily; now all will need to do so.

(Incidentally, the new reporting requirement for ADEs states that pharmacies are not considered “reporters” except when they have contracted with manufacturers to distribute “private label” products. In that case, retailers may authorize the manufacturer or the packer to submit reports as long as the retailer directs all reports it receives to the manufacturer. It will be interesting to see how the FDA regulations on this provision will be written. Stay tuned.)

As for the significance of the two congressional actions, it is clear that the FDA is in the “hot seat” and that the absence of a commissioner—the top political appointee authorized to make things happen—was hampering the agency, especially in terms of drug safety. The fact that the three or four senators who were delaying the nomination for the past year finally let the nominee come up for a vote—he was approved 80 to 11—indicated that even Dr. von Eschenbach’s detractors think that someone is better than no one at the helm of the FDA.

And nothing is more important than revving up the FDA’s postmarketing drug surveillance—in this case, collecting reports on ADEs, of which there will now be more—given the new OTC requirement.

In an effort to step up postmarketing surveillance, the FDA’s wheels have been turning (albeit slowly) because of the absence of a commissioner. For example, the FDA’s valuable MedWatch system, which assembles reports on adverse drug reactions, is not nearly as effective as it could be. Everyone understands that, including Scott Gottlieb, FDA Deputy Commissioner for Medical and Scientific Affairs, who acknowledged as much in a November speech.

The FDA is in the midst of revamping its MedWatch portal. One change will make it easier for pharmacists to tie into the system via their ability to use electronic medical record technology. They will also be able to receive regular updates on ADEs by receiving news of any reports being sent to the FDA as part of its MedWatch system. These updates will be similar to those of the Morbidity and Mortality Weekly Report, sponsored by the Centers for Disease Control and Prevention (CDC). It is not clear how frequently these reports will be disseminated.

Besides attempting to make it easier for pharmacists to send in reports on ADEs, the FDA is trying to expand the kinds of data it reviews. That was the purpose of the proposed rule issued by the Centers for Medicare & Medicaid Services (CMS) in mid-October.

That rule was intended to funnel claims data from Part D prescription drugs to federal agencies that don’t get a peek now. The claims information would be used to validate or reject safety concerns raised about drugs (such as Ketek) and to determine the potential for cost savings in chronic disease management as a result of more effective adherence to recommended prescription drug therapies. Being able to view Part D data might also be useful for (1) identifying groups of beneficiaries who are not receiving evidence-based recommended drug therapies, (2) ascertaining strategies to increase patient adherence to optimal treatments, (3) reducing disparities in health care benefits, and (4) improving health care for all beneficiaries.

Now the FDA will be watching more closely for indications of drug problems and will be passing relevant information along to pharmacists. Congress will also be watching closely. Given the fact that the Democrats have taken control of the House and Senate, and given their express commitment to ratchet up oversight of all federal agencies, Dr. von Eschenbach will be spending plenty of time seeing to it that none of the FDA’s new steps to ensure drug safety cause “adverse reactions” on Capitol Hill.