PUBLICATION

FDA Changes in the New Administration

June 19, 2009

With a Democratic Congress and Administration, the FDA is ramping up its inspection and enforcement activities. Margaret Hamburg has been confirmed as FDA commissioner and Joshua Sharfstein, her deputy, has stated that companies which adulterate products will face criminal prosecution.

Additional monies have been requested by the new Administration to protect the safety of products in the medical supply chain. Additional funding for FDA inspections was recently proposed in the Senate. Senators Charles Grassley and Edward Kennedy support legislation - the Drug and Device Accountability Act of 2009 - which would authorize the FDA to collect inspection fees and proposes authority for FDA inspectors to take action on the spot.

The Obama FY10 FDA budget proposes a huge increase in funding and emphasizes three key areas: more inspection resources for safer drugs and devices; a push for more generic drug approvals and the imposition of user fees with the goal of lowering drug costs; and increased food safety inspection/enforcement activity.

The FDA has increased its staff and has already hired 400 new investigators and scores of compliance staff members.

The FDA is taking steps towards greater openness with the creation of a task force to make recommendations regarding to whom the FDA can release more information concerning FDA drug evaluation determinations and enforcement matters. Two public meetings are proposed, with the first slated for June 24, 2009. Issues of concern include unpublished clinical trial data from drug manufacturers.

Inspections, Injunctions and Warning Letters

Inspections, injunctions and warning letters dropped substantially in the time period from 2001 to 2008. Injunctions and warning letters decreased by almost half and inspections are down by 6,000. There is talk that the FDA warning letter policy will change and the FDA might discontinue the practice (begun in 2002) that all warning letters be reviewed by the FDA Office of General Counsel. This policy led to a 60% decrease in warning letters.

Recent trends in warning letters include emphasis on good manufacturing practices, unapproved new drugs and misbranding. We believe that the FDA will start to look at pharmacovigilance and complaint handling next.

Expect to see an increase in FDA regulation and enforcement in the following areas: bioresearch monitoring; good manufacturing practice compliance; medical device modifications without prior FDA clearance or approval; and off-label promotion of pharmaceutical, biologic and medical device products.

The number of international inspections is on the rise. The FDA opened three offices in China as well as an office in India with additional offices expected in Eastern Europe and South America. The FDA has instituted a *Beyond our Borders* program with more focus on international suppliers as well as foreign manufacturing sites.

The FDA believes that the company, manufacturer or distributor is responsible for finding and correcting problems on their own. The FDA will closely scrutinize effectiveness of a company's quality control functions.

There is a move toward more aggressive use of FDA resources and greater leveraging of the Department of Justice as the FDA's attorney. Recently, the FDA subpoenaed a manufacturer to submit its internal audit reports. The FDA will place more emphasis on the Application Integrity Policy by which it can refuse to review new drug or device applications until the FDA is assured of a company's integrity.

The FDA's expectation is that manufacturers and distributors should have rigorous GMP audit programs for their suppliers. Companies are responsible for and need to reexamine their relationships with third parties and service suppliers.

Expect more emphasis on safety reporting and greater scrutiny on adverse event reporting. The FDA has the authority to require Risk Evaluation and Mitigation Strategies (REMS).

Good Laboratory Practices

On February 6, 2009, the U.S. Court of Appeals for the Fifth Circuit ruled in U.S. v. Palazzo that a clinical investigator can be held criminally liable for failing to comply with FDA regulations that impose record-keeping and reporting requirements for clinical studies. The case establishes the precedent that non-compliance with the Good Clinical Practice record-keeping requirements contained in FDA regulations can result in criminal penalties. This illustrates that the FDA and the DOJ are actively expanding the types of criminal charges that they can bring when they identify non-compliance during the conduct of clinical trials. In the past, federal criminal proceedings against clinical investigators for violating recordkeeping requirements were primarily limited to egregious situations involving blatant falsification of data

Expect increased FDA scrutiny concerning financial disclosures by clinical investigators and study sponsors.

Off-Label Uses

The FDA issued guidance in January 2009 concerning reprints for medical journal reports on unapproved new uses of approved drugs and approved or cleared medical devices. “Unapproved uses” means those uses that are not included in approved labels or statements for intended use.

This guidance offers “good reprint practices” and sets out the parameters for allowable dissemination of such information. Dissemination is allowed if the studies are conducted by independent experts, are peer reviewed, are not funded by the manufacturer, contain full disclosure of the financial arrangements, and are not false or misleading. Statements stipulating that the new use is not FDA-approved or cleared must be included.

The FDA issued proposed guidance in May 2009 concerning the presentation of risk information in prescription drug and medical device promotion. Comments must be submitted to the FDA by August 25, before the FDA finalizes the guidance. The guidance covers advertising and promotional labeling for prescription drugs, ads for restricted medical devices and labeling for all medical devices but does not address over-the-counter drug ads. The guidance details the reasoning the FDA uses when it evaluates whether the risk and benefit presentations in a promotional piece create an accurate “net impression” of a product's risk and benefits.

This draft guidance focuses on how the FDA views promotional materials and specifically discusses such elements as the presentation of headlines and subheadlines; the way that risk information is conveyed regarding the relevance and location of presented risk information; and the impact of the advertisement's format on the consumer and specific target audience.

The FDA and State Cooperation

State attorneys general are aggressively campaigning against off-label promotion, relying on their state consumer protection and/or unfair trade practices laws. Cooperation between the states and the FDA will continue under the new Administration as the state off-label enforcement cases are seen as complementary to the Federal False Claims Acts cases.

ACTION STEPS

How We Can Help You Meet the Challenges of this New FDA Era

Our experienced attorneys can help you navigate the following steps to more effectively meet the challenges of the new FDA era:

- Evaluate promotional materials to scrutinize claims made, ensure fair balance and meet the "reasonable consumer standard" now required by the FDA
- Review key standard operating procedures such as recall, complaint handling and adverse event policies and procedures to ensure adequate protections
- Be vigilant regarding the manufacture of drugs and devices in compliance with good manufacturing practices and good clinical practices and with the appropriate quality systems in place
- Work through FDA deficiency notices received and ensure corrective actions are in line with required regulations, FDA guidance and current FDA initiatives
- Develop internal auditing programs to ensure that your company finds and solves its own problems in advance of Administration or state scrutiny
- Keep abreast of enforcement activity, warning letters and FDA guidances applicable to the manufacture of your specific drug or medical device products
- Be proactive in protecting the company from product liability claims by ensuring the manufacture, distribution, storage, and promotion of your products are in full compliance with applicable Administration and state laws and regulations

For more information, contact your Baker Donelson attorney or any attorney on the Drug, Device and Life Sciences team.