

# DataChem News

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## Problems in the FDA

Without knowing it, each of us interacts with the Food and Drug Administration (FDA) daily. From the food we choose to put in our bodies and on our family's table, to the over-the-counter and prescription medications that we take, we put a lot of faith in the FDA and their ability to protect us as a consumer. What happens when the entity we trust with our well-being is ill and not functioning to the level intended? Drugs are making it to the market faster than ever and, they're being recalled at an alarming rate. Insiders say that the FDA is underfunded and understaffed and, as a result, is unable to effectively operate.

### What the FDA Regulates:

Food  
Drugs  
Vaccines  
Medical Devices  
Blood and Tissue  
Radiation-emitting  
Machines  
Animal Feed  
Animal Drugs  
Cell Phones  
Dietary Supplements  
Biotechnology  
Gene Therapy

### Conflicting Interests -

One major concern centers around funding. The branch of the FDA that regulates new drugs that make it to the market receives a fair amount of funding from pharmaceutical companies. Over half of the FDA's drug review budget is derived directly from the drug manufacturing industry. This funding, known as "user fees," allows for drugs to speed through the approval process and make it to market faster. A process that formerly required 27 months of review is now accomplished in a year; some drugs, like Vioxx, make it to market in six months. Since this increase in the approval rate the FDA has seen an 80% increase in adverse events and a 200% increase in reported deaths.

Another problem centers around the FDA's Advisory Board. The FDA Advisory Board votes on drugs and medical devices. It is comprised of physicians, researchers and patient advocates. A recent study published in The Journal of the American Medical Association (JAMA) found that nearly one in four people on the advisory board had financial ties to the drugs and devices they were voting on or the competitors.

Often times, very well meaning scientists responsible for drug review within the FDA, alert supervisors of the potential dangers of a particular drug. Unfortunately, many of the concerns of the reviewers go unaddressed and the reviewers themselves are often reprimanded.

Congress is taking steps to fix the problems inherent within the FDA. In the meantime, consumers need to be aware that the regulatory body over our food and drug supply is not fool-proof.

This article was taken from Readers Digest "Strong Medicine: What's Ailing the FDA?"

## Analysis of the Month

### Perchlorate

DataChem is offering a 10% discount on perchlorate analysis using EPA method 6850 during the month of April.

For further details contact us at [info@datachem.com](mailto:info@datachem.com)

To take advantage of the offer simply refer to the newsletter in your analytical request. Discount is only available at our Salt Lake facility.



Our Food and Drug Administration reviews the drugs that make it to our pharmacy's but how safe are they?

## Perchlorate Contamination

Perchlorate is both a naturally occurring and manmade contaminant increasing found in groundwater and soil. Most perchlorate manufactured in the United States is used as an ingredient in rocket fuel and missiles. In addition, perchlorate-based chemicals are used in the construction of highway safety flares, fireworks, pyrotechnics, explosives, common batteries, and automobile restraint systems. In concentrations as low as 24 parts per billion (ppb) it impairs thyroid function and inhibits organ development. In newborns and infants it can impair brain development, change behavior and decrease learning abilities. Perchlorate contamination has been found in at least 27 states. In many states, it's not only been detected in groundwater but also in the food chain, including the milk supply. The Food and Drug Administration (FDA) recently tested 300 foods, of the foods tested 75% of them tested positive for perchlorate. A new FDA study released earlier this year suggests that perchlorate levels as low as 4 ppb could have an impact on children under 10. According to the study, children ten and under are the most highly exposed to perchlorate from contaminated food and beverages. This is because children consume items from food groups that are heavily and consistently contaminated with perchlorate, especially dairy foods.

## Additional resources on perchlorate contamination:

ENVIRONMENTAL WORKING GROUP  
<http://www.ewg.org/node/25875>

FOOD AND DRUG ADMINISTRATION  
<http://www.cfsan.fda.gov/~dms/clo4qa.html>

ENVIRONMENTAL PROTECTION AGENCY  
<http://www.epa.gov/safewater/ccl/perchlorate/perchlorate.html>

Sensitivity and Simplicity  
Contact Your Project Manager about the Advantages of using LC/MS for your Next Drug Screen Analysis!