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## WHAT'S BEHIND AN F.D.A. STAMP? THE F.D.A. IS EVERYWHERE THESE DAYS, OR SO IT SEEMS

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The F.D.A. is everywhere these days, or so it seems.

Sellers of dubious medical devices claim in late-night TV advertisements that their products are "registered with the F.D.A."

Some vitamins and homeopathic remedies, many with doubtful benefits, boast on their labels that they are "F.D.A. approved."

In the 1990s, the agency was widely criticized as taking too long to approve new drugs, so Congress passed legislation speeding up drug reviews.

Then in 2004, Merck withdrew its painkiller Vioxx after studies showed the pill increased the risk of heart attacks and strokes.

Critics lambasted the agency, saying it approved medicines too easily and for months delayed issuing warnings about potential drug risks.

The agency now issues a blizzard of risk alerts, but sifting through this information can be difficult. And it can be tough to figure out which products have the agency's crucial stamp of approval - or what bits of product information have actually been vetted by federal regulators.

For instance, the drug information sheets that pharmacists routinely give to patients along with their prescription medicines - the sheets are sometimes printed on receipt paper - seem like official government pronouncements.

But the F.D.A. has no role in writing or overseeing most of these sheets. Public Citizen, a watchdog group, has found that some drug information sheets are dangerously wrong or misleading.

What is a consumer to do?

The F.D.A. is the federal agency charged with overseeing the safety of drugs, medical devices, food, cosmetics and many other health-related products. But although the agency has regulatory authority over nearly 25 percent of the nation's

economy, it is important to understand what it regulates closely and what it doesn't.

For example, the F.D.A. does almost nothing to ensure that dietary supplements work as advertised. Only when supplements are proved to be unsafe or to contain regulated substances can the agency take action.

In the past year, the agency has seized thousands of Asian herbal supplements promoting virility because they contained the active ingredient in Viagra, a regulated substance. Similarly, the F.D.A. exempts over-the-counter homeopathic remedies from its testing. So any reference to the F.D.A. on dietary supplements or homeopathic medicines generally does not mean that the agency has found the products to be safe or effective.

And the sellers of quasi-medical devices or food products that claim their products are "registered" with the F.D.A. may have done little more than send a letter to the agency. The Bioterror Act of 2002 requires food manufacturers to register with the F.D.A., but the agency almost never inspects these facilities or products.

For drugs, the F.D.A.'s role is more complicated. In most cases, the F.D.A. demands that manufacturers seeking to sell drugs in the United States, either over the counter or prescription, prove that they're safe and effective. But there are exceptions, and these can be hard to spot.

A surprising number of older prescription medicines have been around for so long that they have never been vetted by the agency. Officials have promised for decades that they would catch up with these products. But dozens, perhaps hundreds, still remain.

Just last year, the F.D.A. announced that it would force off the market many unapproved products containing hydrocodone, a popular and addictive narcotic often used as a cough suppressant. Many of these products had not been inspected or approved by the agency, and some had labels stating they could be used in children as young as 2, although such products had never been approved for use in preschool children.

Even some products with F.D.A. approval have very little evidence that they work. For instance, when the F.D.A. approved over-the-counter pediatric cold and cough remedies decades ago, its standards were far lower than they are today. Some of the medicines in these products have never proved effective in children, and children have, in rare cases, been harmed by them. The agency is in the midst of a years-long process that could revoke approval of many pediatric cough medicines.

The most challenging situation facing the F.D.A. and consumers is the growing number of reports of adverse reactions to popular medicines. The agency received nearly 500,000 such reports last year, but most were false alarms. Figuring out which signal real safety issues is difficult.

In the past the agency typically said little or nothing about its suspicions of safety issues until top officials concluded that they were real. But several years ago, a midlevel drug safety officer concluded in a report that studies of antidepressants showed that the drugs caused an increase in suicidal behaviors or thoughts in children and teenagers. Top officials suppressed the report and refused to allow the official to testify before an expert committee. A year later, a more thorough study confirmed the risk. When news of the earlier report leaked, the agency was severely criticized.

Top agency officials promised to be more open about potential drug risks. The F.D.A. has sent out public health advisories about potential drug problems and created a consumer information Web site. And under prodding from Congress, it even created a quarterly list of potential drug problems that safety reviewers are in the midst of investigating.

However, a drug's appearance on the list does not mean that the F.D.A. has concluded that the medicine is particularly risky. Rather, it shows that safety officials have some reason to suspect a problem.

"If your doctor has prescribed a drug that appears on this list, you should continue taking it unless your doctor advises you differently," said Janet Woodcock, director of the agency's drug center.

Recently, the F.D.A. has mandated that pharmacists dispense consumer guides with some drugs that explicitly detail medicines' risks. These guides, written by the F.D.A., are often far more comprehensive than the drug information sheets traditionally given by pharmacists.

Safety advocates have been pleased. "Our position is that medication guides should be provided for all drugs, period," said Dr. Peter Lurie, deputy director of the health research group at Public Citizen.