



## Utilizing the FDA Website for Competitive Intelligence Information

By Donna Mitchell-Magaldi, Nerac Analyst

There are many resources available when gathering competitive intelligence. These sources of information include business news, SEC filings, patents, company quarterly report and market reports. However, there is a very important resource that many companies tend to overlook. The Food and Drug Administration (FDA) is a valuable free resource for competitor and competitive product information. The FDA website contains information regarding products that are in the process of seeking approval, products that have been granted market approval, products experiencing adverse event and companies that have been audited by the FDA and have been found noncompliant to regulations. FDA also provides information on warnings and product recalls.

The FDA website "[meetings](#)" provides detailed information via webcasts, meeting transcripts and comments pertaining to up and coming innovative new products and valuable discussions concerning unmet needs. For example, in [September 13, 2012](#), The FDA hosted a teleconference between the FDA and panelist/patient advocates to discuss current treatments and identify unmet needs for the treatment of chronic fatigue syndrome. Patients, physicians and advocates alike were able to voice their needs and concerns with current practices. On [January 28, 2014](#), Merck met with the Allergenic Products Advisory Committee to discuss and present clinical evidence for the approval for their biologic license application for Ragwitek, a sublingual tablet for the treatment of ragweed pollen allergy. The Advisory Committee voted to approve Ragwitek for the treatment of adults age 18-65 years suffering from ragweed allergy.

Newly approved medical devices, drugs and biologics information is also publically available on the FDA website. This is accomplished through the [FDA 510K](#) or [PMA database](#), the CDER's [Orange Book](#) and through the [product approvals page](#) on the vaccines, blood and biologics page in the CBER. The products listed have a link to either a summary of the product or a direct link to the package insert. This resource provides valuable information as to which products are being marketed, the description of the product technology, its intended use and intended patient population. By keeping track of the newly approved devices, drugs and biological products, companies can closely monitor new competitive products that enter the market. This is important when trying to keep notified of any new disruptive technology entering the marketplace.

The FDA is required to inspect companies both in the process of seeking approval for products and for companies whose products are currently on the market. The [FDA findings](#) are posted to the website and available to the public. The FDA warning and violation letters can be searched by company, subject, issuing office, response letters and closeout letters. For example, if searching for "orthopedic", provides information on 77 reports concerning a variety of orthopedic companies and their products. The information in these reports describes the specific products with issues, the nature of the issues, and the time frame in which issues need to be addressed. By searching this database for a specific competitor, information can be

collected as to the number of times the competitor is cited, which products are of concern and obtain a description of the violations. This can prove to be valuable marketing information.

A list of recalls for products either voluntarily or involuntarily removed from the market is also available from the FDA website. There are three classes of recalls. A Class I recall is the most severe as it is defined as “Dangerous or defective products that predictably could cause serious health problems or death (FDA.gov)”. Class II is defined by the FDA as “Products that might cause a temporary health problem, or pose only a slight threat of a serious nature.” And class III defined as “Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws”. Both the [CDRH](#) and [CDER](#) have a database that can be searched. Additionally, each agency has a listing of recalls. For example, the CBER has a recalls webpage that provides a list per year of all the biologic products that have been recalled. This information provides the brands, the lot#, reason for the recall and the manufacturer of the product.

The FDA is a very valuable source of competitor and competitive product information. It provides both business development and marketing individuals with tools to better discern unmet needs from both the medical professional and patient perspective. These advisory meetings, teleconferences and webcasts, provide Medical Professionals a platform to communicate their experience, professional expertise and personal views as to the needs and possible benefits to both the medical industry and to the patients. Through monitoring the new product approvals, companies can keep up to date on their competitors and competitive products that use the same or similar technology but have been expanded to another patient groups or another intended use, thereby increasing their market presence. By monitoring new products approved by the FDA, a company can better identify new disruptive technologies that may interfere in their future market penetration. Keeping updated on competitor warnings, violations and recalls can aid in focusing marketing efforts to achieve better market placement of company products.

The FDA website has a tremendous amount of valuable information and is extremely complicated and time consuming to navigate. Therefore it's important to know what information is available and where to find it. Nerac analysts have extensive knowledge and can mine the FDA data efficiently and effectively providing you with an analysis of important data. The valuable information found on the FDA website affords business development and marketing professionals with a competitive edge. Let Nerac help!

## About the Analyst

### Donna Mitchell-Magaldi

Analyst Donna Mitchell-Magaldi partners with medical device companies, serving them in many capacities. Donna's particular expertise is within the dental field where she was involved all areas of dental hygiene, radiation, and restorative dentistry, oral surgery including implants, extractions, and periodontal treatments, prosthetics and orthodontics. As an Analyst at Nerac, Donna has been exposed to a variety of other medical device disciplines such as cardiovascular, medical imaging, endodontics, biomonitors and medical sensors, orthopedics, gastrointestinal and more. Over the course of the last several years, Donna has been assisting our medical device clients with meeting the MedDev 2.7.1 Rev 3 "Guideline on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies" and other regulatory issues, market analysis, prior art research, research to support R&D initiatives, patient landscape, FDA clinical literature support, and much more. Ms. Mitchell-Magaldi has wide-ranging expertise, encompassing medical device regulatory; dentistry (devices, equipment, procedures, dentifrices, hygiene, impressions, prosthetics, implants, orthodontics, periodontals); medical devices (including imaging diagnostics, catheters, shunts, and syringes); radiography; environmental topics (the effects on wildlife and habitation, strategies to protect endangered ecosystems, species, and food-chain effects); ecology (population dynamics, animal behavior and organismal biology); and laboratory analysis (trace metal analysis, IACUC, lab safety, inductive couple plasma and atomic absorption).

### Credentials

B.S., Biology, Eastern Connecticut State University

## About Nerac

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