FDA launches new interactive, PDF-based, 510(k) submission template

[Sort-of, maybe, could be ~]

February 26, 2020

Media Inquiries

Britney Manchester
301-796-1026

The following quote is attributed to Jeffrey Shuren, M.D., J.D., and director of the FDA’s Center for Devices and Radiological Health:

“As technology advances, the FDA must keep pace with the increasing complexity of rapidly developing technology and continue to modernize and evaluate our programs and processes, ensuring they continue to be efficient, consistent and scientifically rigorous.”

“To promote these goals, we’re launching a new optional 510(k) submission template that allows pilot participants to submit applications to the FDA using a more dynamic electronic format capable of organizing the complex information necessary for a robust scientific review. Without changing our statutory or data requirements, this highly-interactive submission template is intended to allow manufacturers to provide information to the FDA that’s complementary to CDRH internal review templates currently used to review 510(k)s, allowing us to receive information and evaluate the submission more efficiently and consistently.

“The template, referred to as the electronic Submission Template And Resource (eSTAR), will be released as part of an eSTAR Pilot Program. eSTAR is intended to improve our overall productivity, enabling the agency’s review staff to put more of our time and resources into evaluating applications for devices that pose the highest potential risks to patients. Additionally, eSTAR is a step toward fulfilling our Medical Device User Fee Amendments of 2017 (MDUFA IV) commitment to streamline the premarket notification review submission process, which is also part of the FDA’s ongoing effort to ensure that we’re giving patients more timely access to safe, effective and high-quality medical devices.”

• Today, the U.S. Food and Drug Administration is announcing the voluntary electronic Submission Template And Resource (eSTAR) Pilot Program as an alternate method available for selected industry participants in the pilot to prepare a 510(k) submission. The FDA will select up to nine participants who provide a holistic representation of the medical device industry and meet the pilot selection criteria.

• With an eSTAR, the content of the premarket submission is embedded within a PDF document, which allows applicants more dynamic functionality when developing, viewing and editing a 510(k). eSTAR templates are designed and structured in a similar format as the FDA reviewers’ template, thereby improving consistency in FDA’s review of these premarket submissions.

• Submissions using an eSTAR do not change any statutory or data requirements for device sponsors to demonstrate their devices are substantially equivalent to a predicate device. However, a Refuse to Accept review (a preliminary review used to ensure the submission is complete) will not be conducted on eSTAR templates submitted as part of the pilot.
The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

SIC. OK, the FDA made a run at this a few years back and it just faded away, maybe this time it will stick, stay tuned.

**CDRH Learn**

CDRH Learn, FDA's Center for Devices and Radiological Health (CDRH) web page for multimedia industry education. CDRH Learn is our innovative educational tool, which consists of learning modules describing many aspects of medical device and radiation emitting product regulations, covering both premarket and postmarket topics. This tool is intended to provide industry with information that is comprehensive, interactive, and easily accessible. Modules are provided in various formats, including videos, audio recordings, and slide presentations. CDRH will determine the most appropriate format for the particular topic being presented, and will post the learning module on this site to meet your educational needs!

Go to: [https://www.fda.gov/training-and-continuing-education/cdrh-learn](https://www.fda.gov/training-and-continuing-education/cdrh-learn)

**Tips for Viewing Modules**

Modules should be compatible with most devices (computers, tablets, smart phones). We recommend you use Mozilla Firefox or Google Chrome to view modules. If you encounter a viewing error, we suggest you try another browser.

SIC. This is a really good information source; the FDA has done a good job.

**MDR Resource Center EMERGO BY UL EU Medical Devices Regulation 2017/745 (MDR) resource center**

In May 2020, the European Medical Devices Regulation 2017/745 (MDR) will apply in the world’s second-largest medical device market. The new Regulation will introduce major changes to how medical device manufacturers obtain CE Marking and maintain access to the European market, and yet a majority of companies may have yet to prepare for compliance to these new requirements or organize their regulatory transition strategies.

In May 2020, the European Medical Devices Regulation 2017/745 (MDR) will apply in the world’s second-largest medical device market. The new Regulation will introduce major changes to how medical device manufacturers obtain CE Marking and maintain access to the European market, and yet a majority of companies may have yet to prepare for compliance to these new requirements or organize their regulatory transition strategies.

Key MDR compliance requirements and challenges

An effective road map to MDR compliance involves multiple components. MDR requirements, such as conformity assessments and sufficient clinical evidence, are more expansive and complex than those of the MDD, which means manufacturers must now address issues including:

- Total product lifecycle approach to CE Marking certification
- Learn how MDR affects human factors engineering and usability requirements via our this webinar
- Enhanced post-market surveillance and post-market clinical follow-up (PMCF) requirements
- Notified Body capacity: When does your NB plan to obtain MDR designation?
- Changes to European Authorized Representative (AR) roles and agreements
- Eudamed database submission requirements for manufacturers, devices and other economic operators

Are you prepared? Learn how far your company has to go to reach MDR compliance with our MDR Readiness Checklist.

**Triad medical devices company fined $50,000 as part of federal investigation**

A.K.A. A world of hurt will show up with Ray-Bans and dark clothing.

A Greensboro biotechnology company, Carolina Liquid Chemistries Inc., has been ordered to pay a $50,000 fine by a federal judge after pleading guilty to a charge involving distributing and selling adulterated medical devices.

The company, a tenant in Innovation Quarter in downtown Winston-Salem until 2017, was investigated by the U.S. Justice Department and Food and Drug Administration.

The FDA sent Carolina Liquid a warning letter July 31 stating its claims against the company. A legal complaint was filed Aug. 26, with a plea agreement being reached Sept. 3 and sentencing occurring Dec. 12.

The company, founded in 1997 and based at 313 Gallimore Dairy Road, is led by chief executive and president Phil Shugart. It also has operations in Brea, Calif., and has 44 employees overall.

Carolina Liquid provides chemistry instruments and reagents for use in reference laboratories and clinical laboratories located in hospitals and physician offices.

According to the plea agreement, the company admitted to developing systems for testing human urine for drugs of abuse and then, from 2010 to 2014, marketing the systems. The integrating of the systems was done without pursuing required FDA approval, which company officials admitted.
“FDA’s device approval requirements are designed to ensure the safety and effectiveness of devices used by Americans,” FDA Special Agent Lisa Malinowski said in a statement.

“(The) announcement serves as a reminder of the FDA’s continued focus on taking action against companies that put profits ahead of the public health.”

The plea agreement represents the conclusion of a 10-year-old investigation that was kept mostly under wraps outside court documents filed in May 2014 that the Winston-Salem Journal reported on at the time.

Those documents centered on a raid in which chemicals, documents, electronic devices and client communications were seized.

The charge to which the company and Shugart pleaded guilty was introduction and delivery for introduction of adulterated devices into interstate commerce.

U.S. Magistrate Judge Joseph Spero of San Francisco ordered in December that the company serve a two-year probation. It is required to submit to the court an effective compliance and ethics program, as well as submit to unannounced examinations of its books and records.

Fine

According to court documents, the company faced a maximum $200,000 fine. The company’s attorney, David Freedman, recommended a $20,000 fine to the judge, citing the company has successfully completed FDA audits as recently as June 2019. U.S. attorney Benjamin Kingsley said in his sentencing memorandum that Carolina Liquid “sold products without seeking FDA approval for a period of approximately five years.”

“This was not isolated conduct, as CLC received a warning letter from the FDA in 2006 (before the conduct of this case), and a warning from the FDA in 2019 (after the conduct in this case).”

Kingsley said while the “underlying charge here is a technical regulatory offense, the requirement of FDA approval before the sale of medical devices is a significant prophylactic measure, designed to prevent the sale of unsafe, ineffective, misbranded or fraudulent products.”

The legal complaint did not list how much revenue Carolina Liquid gained from the sales of what were determined to be adulterated devices. Although Kingsley cited the philanthropic contributions by Phil Shugart and his wife, Patti, and their cooperation including the guilty plea, “there is no indication that the entity has disciplined any officer, director, employee or agent responsible for the offense.”

Freedman, in his Dec. 3 sentencing memorandum, cited that a fine greater than $20,000 would be burdensome to the company.

Freedman said the company “has suffered financial and other losses as a result of the extensive investigation underlying this case.”

Investigation

According to legal documents, the May 7, 2014, raid was part of the federal investigation into alleged wire and health care fraud worth an estimated $135 million. Agents also executed search warrants at the couple’s home on Windsor Road.

Besides the FDA, agencies involved in the raid included the Federal Bureau of Investigation, the U.S. Department of Health and Human Services, the Office of the Inspector General and the U.S. Defense Department.

All court documents were ordered sealed May 9, 2014, by federal judge Patrick Auld for the Middle District of N.C. There have been no document filings since in that case. Freedman said the documents were “mistakenly unsealed, causing tremendous negative publicity. Competitors seized upon the news article to drive away CLC customers.”

The affidavit said Carolina Liquid’s business practices represent a violation of the federal Food Drug and Cosmetic Act.

Agents said the company misrepresented its products’ capabilities, causing or leading those clients to bill health insurance companies at a rate that, in some cases, was about five times more than allowed.

An affidavit filed by FBI Special Agent Edmund Ewing said the company and its employees made false representations to physicians’ offices about its urine drug-testing systems since at least March 2009.

The company told clients that they could seek higher reimbursement from Medicare and other health insurance companies by using billing codes that are set aside for quantitative testing, the affidavit said.

The affidavit featured other emails from Patti Shugart in which it appears she is also attempting to justify higher billing.

Investigators recorded a meeting in which company officials try to persuade a potential client that it can provide a quantitative drug result, and that the client could apply for a higher reimbursement.

Freedman said in his sentencing memorandum that because of the negative publicity, the company’s workforce was reduced from 90 employees in 2014 to 44 employees now.

In justifying his recommendation of a $20,000 fine, Freedman said “CLC incurred substantial expenses, including the cost of obtaining regulatory advice, experts and legal fees.”

He said the Shugarts “have weathered the emotional and financial toll of an extensive regulatory investigation.”

SIC. A clear case of ‘what can go wrong - will.’ You have been warned.