O R A C L E

Established 1988, Experience matters

NEWSLETTER FROM DELPHI CONSULTING GROUP (DCG)

An Internet Based Medical Device Regulatory Service, www.delphiconsulting.com

Vol. 25 Issue 5 May 2019

The ORACLE is a free newsletter of recent medical device regulatory & computer information that is of interest to designers, and device manufactures.

Delphi Consulting Group (DCG), provides medical device regulatory (FDA) release to market via the 510(k) and PMA pathways. DCG is Internet based to boost efficiency and reduce costs

FDA Form 483s could get easier for medical device companies: Here's how

April 22, 2019 By Chris Newmarker Leave a Comment

FDA in the U.S. is setting up a formal way for medical device companies to get nonbinding feedback about Form 483s, which raise potential manufacturing process problems.

FDA is taking comments through today about the draft guidance, which it issued Feb. 19 under a requirement in the FDA Reauthorization Act of 2017.

The proposed process actually standardizes what some in the industry have been doing for a long time: seeking nonbinding feedback from FDA about inspection results and proposed solutions, in the same way a company might hold a presubmission meeting, according to Mike Drues, a Southern California–based regulatory consultant who has worked with both companies and FDA.

"We've had the opportunity to have these types of conversations in the past, but not in a formal or organized way," Drues, who is president of Vascular Sciences, explained to ***Medical Design & Outsourcing*** late last month.

Is the Government All Fired Up About Charging Individuals?

Posted: 11 Apr 2019 03:30 AM PDT

By Riëtte van Laack & JP Ellison & Anne K. Walsh —

We have long posted about the government's threats to hold individuals liable for actions taken on behalf of their companies, for example here, but these actions remain rare and typically are reserved for egregious, repeated, and intentional criminality. A recent indictment against two former executives, however, may signal the government is making good on its threat even when the conduct (at first glance) involves mundane recordkeeping or reporting obligations.

The U.S. Consumer Product Safety Commission (CPSC) has long had the authority to bring criminal charges for knowing or willful violations of the Consumer Product Safety Act (CPSA). Indeed, the government has used this power to charge parties for things like repeated importation of banned consumer products into the United States. But the CPSC has never used its criminal authority to charge individuals for failing to report information to CPSC about potentially defective products. Until recently.

On March 28, the government filed an indictment against Simon Chu, the Chief Administrative Officer, and Charley Loh, the Chief Executive Officer, of "unindicted co-conspirator" companies that sold dehumidifiers to US consumers. According to the indictment, as early as September 2012, Chu, Loh, and their companies received multiple reports that their Chinese dehumidifiers were defective, dangerous, and could catch fire. The defendants then conducted testing that confirmed that these dehumidifiers could pose safety issues.

Section 15(b) of the CPSA requires manufacturers, importers, and distributors (and their individual directors, officers, and agents) to report "immediately" to the CPSC information that reasonably supports the conclusion that a consumer product contains a defect that could create a substantial product hazard or creates an unreasonable risk of serious injury or death. The defendants allegedly knew of the reporting obligations under the CPSC, but not only failed to report the incidents to the CPSC as required, but made affirmative representations to the CPSC that the humidifiers were not defective and hazardous. In addition, Chu and Loh continued to sell these products for at least six months, and provided retailers with false certifications that the products met safety standards.

Even though the government touts this case as the "First-Ever Criminal Prosecution for Failure to Report" under the CPSA, the allegations describe much broader criminality of lies and cover-ups. Indeed, although the manufacturer companies are unnamed in the indictment, it appears they are the same companies that agreed to settle with the CPSC a few years ago for the same conduct. The $15.4 million paid by Gree Electric Appliances Inc., of Zhuhai, China; Hong Kong Gree Electric Appliances Sales

Delphi Consulting Group, Houston, Texas 77071-3404

Contact: J. Harvey Knauss, +(832) 675-9281 voice, info@delphiconsulting.com or www.delphiconsulting.com

Co. Ltd., of Hong Kong; and Gree USA Sales Ltd., of City of Industry, Calif., was the highest civil penalty ever imposed under the CPSA. As part of the settlement, these companies agreed to "implement and maintain a compliance program designed to ensure compliance with the CPSA and regulations enforced by the Commission with respect to any consumer product manufactured, imported, distributed, or sold by Gree," which included a variety of compliance provisions related to reporting.

So perhaps this case is not as ground-breaking as advertised given the full story. Nevertheless, it serves as a useful reminder to company executives that the risk of criminal exposure is real.

US FDA issues finalized list of Class I medical device accessories

Regulatory Updates | Medical Devices
Apr 15, 2019 by Stewart Eisenhart

EMERGO BY UL SUMMARY OF KEY POINTS:

· FDA finalizes Class I classification for some medical device accessories;

· Class I designations take effect May 13, 2019;

· Additional accessories may be identified for low-risk classification by 2024.

The US Food and Drug Administration has published a finalized list of accessories to be designated as low-risk Class I medical devices in accordance with the FDA Reauthorization Act of 2017 (FDARA).

FDA's final rule will go into effect May 13, 2019.

Class I eligibility criteria for medical device accessories

FDA identified Class I classification criteria for accessories based on the following requirements:

· The accessory is not used to support or sustain human life, or is important in prevention of impairment to health;

· The accessory does not pose a potential risk of illness or injury;

· General controls can sufficiently provide reasonable assurance of the accessory's safety and effectiveness.

The list of accessories to fall under Class I classification includes gastroenterology-urology accessories; ureteral stent accessories; implanted mechanical and hydraulic urinary continence device surgical accessories; air-handling apparatus accessories; and corneal inlay inserter handles.

Within five years, FDA plans to propose additional medical device accessories appropriate for Class I designation.

Get the Latest Regulatory Educational Materials from CDRH

The Division of Industry and Consumer Education (DICE) at the FDA's Center for Devices and Radiological Health (CDRH) recently developed or updated the resources below to provide you the latest and most accurate educational information about medical devices and radiation-emitting electronic products.

CDRH recently posted these pages in Device Advice:

A History of Medical Device Regulation & Oversight in the United States (8/27/2018)

510(k) Pilots (10/22/18)

Reduced Medical Device Program Update (10/25/2018)

Standards and Conformity Section (10/29/2018)

PMA User Fee Refunds (12/12/2018)

PMA Supplements and Amendments (12/14/2018)

Accreditation Scheme for Conformity Assessment (12/14/2018)

CDRH recently released the following learn modules in these categories:

The Basics

How to Complete Form FDA 3602: MDUFA Small Business Qualification and

Certification for a Business Headquartered in the United States (10/25/2018)

Postmarket Activities

Overview of the Quality System (11/19/2018)

Production and Process Controls (11/19/2018)

Documents, Change Control, and Records (11/19/2018)

Radiation-Emitting Products

How to Get Your Electronic Product on the U.S. Market (10/16/2018)

510(k) Third Party Program (for Third Party Review Organizations)

510(k) Third Party Review Program: Overview (10/16/2018)

X-Ray Systems (10/16/2018)

You, me, and everybody and the Internet

As we all know the large Internet players – Google, Amazon, Microsoft, etc., know more about us than we do, and they sell this information to any and all. We kill time roaming around the Internet looking at this and that. Then you check e-mail and there is what you look at without or with interest bugging you to buy, use, give to, and on and on. Yes, you can turn on 'block ads' in most browsers, but they do little. There is one search engine that does not save, sell, or keep anything you search for it is DuckDuckGo. DuckDuckGo works as well as Google and prevents what you searching for from showing up in other programs, or on company servers. Then if you use the **Brave** browser all ads are really blocked. However, some web pages will not work under this condition, and you must take the shields down. Currently the Brave browser is a work-in-progress and has some issuers. Just good to know.