O R A C L E

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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 gives certain device makers more time to add UDIs

July 1, 2020 *By* ***Nancy Crotti***

The FDA said today that it will grant manufacturers of Class 1 and unclassified medical devices and certain others more time to add unique device identifiers (UDIs) to their products.

These companies will now have until Sept. 24, 2022 to comply with the agency's UDI rule, including standard date formatting, labeling and Global Unique Device Identification Database (GUDID) data submission requirements. The new guidance, published here, revises guidance issued in 2018. It also covers certain devices that require direct marking, but does not include implantable, life-sustaining, or life-supporting devices.

The FDA implemented a final rule in 2013 requiring UDIs on most medical devices, including updated labeling designs and requiring that certain information be submitted to GUDID. The national UDI system is intended to provide structure to improve best practices, including in care and delivery of medical devices and is especially important for high-risk implantable devices.

The latest guidance, titled "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff," is immediately in effect.

Struggling with Quality Compliance? This Pilot Study Is for You

The Medical Device Innovation Consortium is seeking manufacturers to participate in a new pilot study intended to help manufacturers who have had trouble achieving and sustaining quality compliance.

A new pilot program, a spinoff of the existing Case for Quality Program, is now accepting applications from medical device manufacturers who need help with quality compliance.

Launched in July, the new Accelerate Sustainable Capability (ASC) pilot study is intended to help manufacturers who have difficulty achieving and sustaining regulatory compliance receive insight to help them improve product quality and safety; reach quality compliance more efficiently; structure their systems for continuous quality improvement.

Manufacturers interested in participating in the ASC pilot study can apply here through the Medical Device Innovation Consortium (MDIC), a public-private partnership that works with government and industry stakeholders to improve patient access to innovative medical technologies. The application period will be open until nine sites have been approved for participation.

MDIC said the goal is to test a methodology for providing systemic improvement to enable FDA 483 and/or advisory actions to be closed faster and more sustainably while, at the same time, ensuring objective metrics and residual risk assessments are in place to provide the agency with oversight of product quality throughout the process.

Benefits of participating in the ASC pilot study

MDIC will cover the costs of the Capability Maturity Model Integration appraisal and other activities conducted under the pilot. This includes the development of an action plan that is agreed upon with FDA, and that is intended to address any FDA inspectional observations, concerns communicated in FDA advisory actions, CMMI appraisal gaps, and residual risk assessment concerns.

During the pilot study, FDA intends to forgo planned routine inspections for participating manufacturers. However, the agency said it will continue to conduct "for cause" inspections of such manufac-

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turers as necessary and appropriate. Participants will have the opportunity to complete the improvements to product quality and safety as specified on their action plan.

Additionally, the participating manufacturer may request a Certificate for Foreign Governments, if needed.

Who should apply for the quality compliance pilot study?

Any medical device manufacturer that wants help in achieving and sustaining quality compliance is encouraged to apply, MDIC noted.

MDIC said these manufacturers must have an established Quality Management System that is in accordance with 21 CFR Part 820.

Interested manufacturers will be considered on a first-come, first-served basis with a preference for manufacturers that meet these test case scenarios:

- Two (or more) voluntary self-reporting manufacturers: Manufacturers of any size that self-identify major deficiencies with quality compliance as defined in the **Compliance Program 7382.845**
- Two (or more) manufacturers that received an FDA 483 during a recent inspection: Manufacturers of any size that have major deficiencies with quality compliance as defined in the Compliance Program 7382.845 observed in inspection but with no advisory action yet issued by FDA.
- Two (or more) manufacturers for whom FDA has issued an advisory action: Manufacturers of any size with an open warning letter or untitled letter from FDA, or manufacturers with whom FDA has requested a regulatory meeting as defined in chapter 4 and 10 of the Regulatory Procedures Manual.

The pilot will also consider a mix of domestic and foreign manufacturers when possible. MDIC said it seeks participation from a variety of companies and product types (such as Class III, II, I, diagnostics, disposables, and implants).

There is no fee to apply and manufacturers should expect to be notified of their application's status within one to two weeks. Companies wanting more information about the study may contact Alan Baumel, director of MDIC's Case for Quality Program at abaumel@mdic.org.

FDA Announces Resumption of Domestic Inspections – Will Foreign Inspections Soon Follow?

By Mark I. Schwartz —

On July 10th, FDA announced its goal of restarting domestic on-site inspections beginning the week of July 20th. The regions of the U.S. that will be on the receiving end of these inspections are those that the agency's rating system demonstrates are the safest for conducting prioritized inspections. Apparently, the rating system assesses the number of COVID-19 cases in localities based on both state and national data.

The Advisory Level is based upon the outcome of three metrics: Phase of the State (as defined by the White House guidelines) and statistics measured at the county level to gauge the current trend and intensity of infection. When each of these is taken into consideration, the FDA will identify regulatory activities that can occur within the given geographic region. The three main categories of regulatory activity at the county level will be: mission critical inspections only, all inspections with caveats to help protect staff who have self-identified as being in a vulnerable population and resumption of all regulatory activities.

This is all well and good, but the bulk of inspection sites, particularly drug and biologic manufacturing facilities, are outside the United States, and that's where the major backlog is. Indeed, according to Congressional testimony provided by FDA officials in June of this year, the U.S. only accounted for one quarter of all Active Pharmaceutical Ingredient (API) manufacturing, and less than half of all Finished Dosage Form (FDF) manufacturing.

It remains unclear when on-site foreign drug and biologic inspections will resume, but arguably, FDA should be able to restart those soon based on the same principles FDA has outlined above regarding domestic inspections. In countries where the testing is widespread and reliable, where epidemiological information from such governments can be trusted, and where the data shows an analogous concentration of COVID-19 cases as what is considered acceptable for domestic inspections, FDA should be able to resume on-site foreign inspections. Of course, FDA investigators will need to be able to get to their foreign destinations, meaning that the entry of Americans into the countries in question will need to be permitted.

Failing a resumption of foreign on-site inspections soon, it is unclear what FDA's plan is to resolve the existing backlog, and that is presumably worsening by the week. As a result of the COVID-19 pandemic, FDA suspended foreign on-site inspections in early March of this year, except for those deemed "mission critical."

It is also reasonable to assume that this suspension in inspections has, or will soon be, worsening the drug shortage situation, as foreign manufacturing facilities that have been designated by FDA as Official Action Indicated (OAI) are generally unable to obtain approval of Abbreviated New Drug Applications, New Drug Applications and Biologics License Applications without an improvement in facility status to Voluntary Action Indicated (VAI). Furthermore, these facilities are hampered from taking on new drug development opportunities as sponsors

are reluctant to risk contract manufacturing with a facility for which they do not see a plausible end to OAI status (i.e., little chance for quick FDA re-inspection).
Furthermore, FDA appears unwilling, or unable, to use its statutory authority under section 706 of Food and Drug Administration Safety and Innovation Act (FDASIA) (codified at 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA)) to conduct so called "record review" to resolve the OAI status at these facilities.
(4)(A) Any records or other information that the Secretary may inspect under this section from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug shall, upon the request of the Secretary, be provided to the Secretary by such person, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such person. The Secretary's request shall include a sufficient description of the records requested. [emphasis added]
Indeed, FDA officials have been quoted over the past few weeks as saying that if the FDA is not on-site at the manufacturing facility, then whatever remote FDA facility review takes place "cannot be an inspection" for purposes of the FDCA, and therefore presumably cannot resolve a firm's OAI status. That seems like an unduly restrictive interpretation of the agency's statutory authority. Arguably, if FDA had maintained such a restrictive construction of the FDCA over the 80 years since its enactment, the agency would have had to abandon some of the authority it currently exercises and takes for granted.

In summary, one of three occurrences are likely over the coming months: either on-site foreign inspections will resume; FDA will loosen its overly restrictive interpretation of section 704(a)(4) of the FDCA regarding "record review"; or we can expect a worsening of America's drug shortage and a slowing of the availability of new drugs. Here's hoping that it won't be the latter.

Lifespan Pays $1,040,000 to OCR to Settle Unencrypted Stolen Laptop Breach

Lifespan Health System Affiliated Covered Entity (Lifespan ACE), a non-profit health system based in Rhode Island, has agreed to pay $1,040,000 to the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) and to implement a corrective action plan to settle potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules related to the theft of an unencrypted laptop. Lifespan ACE includes many healthcare provider affiliates in Rhode Island, and has designated itself as a HIPAA affiliated covered entity.

On April 21, 2017, Lifespan Corporation, the parent company and business associate of Lifespan ACE, filed a breach report with OCR concerning the theft of an affiliated hospital employee's laptop containing electronic protected health information (ePHI) including: patients' names, medical record numbers, demographic information, and medication information. The breach affected 20,431 individuals.
OCR's investigation determined that there was systemic noncompliance with the HIPAA Rules including a failure to encrypt ePHI on laptops after Lifespan ACE determined it was reasonable and appropriate to do so. OCR also uncovered a lack of device and media controls, and a failure to have a business associate agreement in place with the Lifespan Corporation.
"Laptops, cell phones, and other mobile devices are stolen every day, that's the hard reality. Covered entities can best protect their patients' data by encrypting mobile devices to thwart identity thieves," said Roger Severino, OCR Director.
In addition to the monetary settlement, Lifespan has agreed to a corrective action plan that includes two years of monitoring. The resolution agreement and corrective action plan may be found at: https://www.hhs.gov/sites/default/files/lifespan-ra-cap-signed.pdf - PDF*.
* People using assistive technology may not be able to fully access information in this file. For assistance, contact the HHS Office for Civil Rights at (800) 368-1019, TDD toll-free: (800) 537-7697, or by emailing OCRMail@hhs.gov.
Footnotes

- 1. Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of 45 CFR Part 164. See 45 CFR 164.105(b)(1).

FY 2021 MDUFA User Fees

The Fees for Fiscal Year 2021 (October 1, 2020 through September 30, 2021) have been released. The fees have increased, what a surprise, just what is needed in these trying times. A copy is attached in both Word and PDF file format to this issue of the Oracle.

Now we have this, i.e., your government in action

To administer unemployment benefits, some states are using aging mainframe [Big Iron], computes programmed in COBAL language more than 50 years old. Connecticut had to recruit retirees who know how to program in the language. Folks, the check will not be in the mail any time soon.

Be Smart, Be Safe, Be Home.